UNITED STATES OF AMERICA
DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

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CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

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NATIONAL MAMMOGRAPHY QUALITY ASSURANCE
ADVISORY COMMITTEE

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MEETING

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THURSDAY,
SEPTEMBER 28, 2000

The Advisory Committee met at 9:00 a.m. in the Walker/Whetstone Rooms of the Holiday Inn Gaithersburg, Two Montgomery Village Avenue, Gaithersburg, Maryland, Dr. Barbara Monsees, Chair, presiding.

PRESENT:

BARBARA MONSEES, M.D.	Chair
CAROLYN BROWN-DAVIS, B.A.	Consumer Rep.
KAMBIZ DOWLAT, M.D.	Member
NANCY J. ELLINGSON, R.T.	Member
PATRICIA HAWKINS, M.P.H.	Consumer Rep.
DEBRA M. IKEDA, M.D.	Member
AMY F. LEE, M.D.	Member
ELLEN G. MENDELSON, M.D.	Member
MICHAEL H. MOBLEY, M.P.A.	Member
ROBERT NISHIKAWA, PH.D.	Member
ROBERT J. PIZZUTIELLO, JR., M.S.E.E.	Member
DONALD C. YOUNG, M.D.	Member
CHARLES FINDER, M.D.	Executive Sec.

FDA REPRESENTATIVES:

HELEN J. BARR, M.D.
STEPHANIE BELLELA, M.S.
KISH CHAKRABARTI, PH.D.
KAYE CHESEMORE, M.B.A.
ANGELA CLINGERMAN
KATHY FRANKE
WALLY MOURAD, PH.D.

OTHER SPEAKERS:

PRISCILLA BUTLER, M.S. American College of Radiology
JUDY DESTOUET, M.D. American College of Radiology
HERSCHEL LAWSON, M.D. CDC
RICHARD LIPPERT

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P-R-O-C-E-E-D-I-N-G-S

(9:00 a.m.)

DR. MONSEES: Good morning. Welcome to the National Mammography Quality Assurance Advisory Committee Meeting. The first item on the agenda is for Dr. Finder to make some statements.

DR. FINDER: I'm going to be reading the Conflict of Interest Statement.

The following announcement addresses conflict of interest issues associated with this meeting and is made a part of the record to preclude even the appearance of any impropriety.

To determine if any conflict existed, the agency reviewed the submitted agenda and all financial interest reported by the committee participants. The conflict of interest statutes prohibits special Government employees from participating in matters that could affect their or their employer's financial interest.

However, the agency has determined that participation of certain members and consultants the need for whose services outweighs the potential

conflict of interest involved is in the best interest of the Government.

Therefore, waivers permitting full participation in general matters that come before the committee have been granted for certain participants because of their professional affiliations or their financial involvements with organizations that could be affected by the committee's deliberations.

These individuals are Drs. Barbara Monsees, Peter Dempsey, Helen Mendelson, Kambiz Dowlat, Robert Nishikawa, Amy Lee, Debra Ikeda, and Donald Young, Ms. Patricia Hawkins, Ms. Nancy Ellingson, Mr. Michael Mobley, and Mr. Robert Pizzutiello.

Out of an abundance of caution we have also limited Dr. Dowlat's, Dr. Nishikawa's, Dr. Ikeda's, and Mr. Pizzutiello's participation in equipment standards because of their involvement with mammography devices.

They are allowed to discuss mammography technologies including digital devices as well as talk about their observations and experiences with these

products. However, they must refrain from voting on specific equipment standards.

Mr. Pizzutiello must also refrain from those discussions involving 2002 criteria and evaluation of personnel competency. Copies of the waivers may be obtained from the agency's freedom of information office, Room 12A-15 of the Parklawn Building.

Several of our members and consultants have also reported that they received compensation for lectures they have given or will give on mammography related topics. However, they have affirmed that these lectures were offered because of their expertise in the subject matter and not because of their membership on the committee.

In the event that the discussions involve any other matters not already on the agenda in which an FDA participant has a financial interest. The participant should excuse him or herself from such involvement and the exclusion will be noted for the record.

With respect to all other participants we

ask in the interest of fairness that all persons making statements or presentations disclose any current or previous financial involvement with accreditation bodies, states doing mammography inspections under contract to FDA, certifying bodies, mobile units, breast implant imaging, consumer complaints, and mammography equipment.

DR. MONSEES: Thank you. We have some new panel members so I would like to just briefly have people introduce themselves. I'll start with myself. I'm Barbara Monsees. I'm a radiologist at Washington University Medical Center in St. Louis. We'll start at this end of the table, please.

MS. BROWN-DAVIS: I'm Carolyn Brown-Davis. I'm the Executive Director --

DR. MONSEES: Could you speak into the microphone?

MS. BROWN-DAVIS: Oh, I'm sorry. I'm Carolyn Brown-Davis. I'm the Executive Director of Breast Cancer Resource Committee, advocacy group for African-American women with breast cancer.

DR. DOWLAT: I'm Kambiz Dowlat. I'm a

surgeon at Rush Presbyterian St. Luke's Medical Center in Chicago.

MR. MOBLEY: I'm Mike Mobley. I'm the retired director of Division of Radiological Health in Tennessee and a private consultant now.

DR. MENDELSON: I'm Ellen Mendelson. I'm a radiologist in practice in Pittsburgh at the Western Pennsylvania Hospital.

MS. HAWKINS: I'm Patricia Hawkins. I'm with the Oklahoma State Department of Health.

DR. FINDER: I'm Charles Finder. I'm a radiologist and the Executive Secretary of this committee.

DR. IKEDA: I'm Debra Ikeda. I'm a radiologist at Stanford University Medical Center and Director of Breast Imaging.

DR. YOUNG: I'm Don Young. I'm a clinical professor of radiology at the University of Iowa College of Medicine where I direct the Breast Imaging and Diagnostic Center.

DR. NISHIKAWA: I'm Bob Nishikawa and I'm a Medical Physicist University of Chicago.

DR. LEE: I'm Amy Lee. I used to be a OB/GYN but I'm a current Program Director of a Master Public Health Program.

MS. ELLINGSON: I'm Nancy Ellingson. I'm from Albuquerque, New Mexico. I work for the American Society of Radiologic Technologists and I am a mammographer.

MR. PIZZUTIELLO: Bob Pizzutiello. I'm a medical physicist in private practice in Rochester, New York.

DR. MONSEES: Thank you. Do you have any comments on alternative standard requests or any other business at this time?

DR. FINDER: No. Basically to say that since the January meeting the division has not approved any alternative standards so we are done with that session.

DR. MONSEES: We'll move on then to the open public hearing segment this morning. I understand we have a public speaker.

DR. FINDER: Dr. Destouet.

DR. MONSEES: We now know who you are.

State your full name and say who you are representing, please.

DR. FINDER: And also if you could spell it for the transcriptionist.

DR. MONSEES: Right.

DR. DESTOUET: Good morning, Madam Chair and committee members. My name is Judy Destouet, D E S T O U E T. I'm representing the ACR, American College of Radiology.

I'm here to address the personnel competency issue under MQSA. My name is Judy Destouet and I'm a private practice radiologist in a large group in the Baltimore area. I have over 20 years of experience in mammography and currently interpret approximately 2,000 mammograms every month.

My practice performed over 100,000 mammograms in 1999. On October 1st of this year I will take over the chair of the American College of Radiology's committee on mammography accreditation.

Should the FDA be looking at the competency of individual physicians, technologists and medical physicists in addition to the required

qualifications, continuing education, and experience outlined in the regulations.

I believe that this is a very unsettled area and one that should be considered very carefully. High quality mammography is dependent on a number of different important interrelated factors within a facility.

Can you hear me?

DR. MONSEES: Yes.

DR. DESTOUET: They include the mammography equipment and film screen processor systems, appropriate use of quality assurance processes to monitor equipment performance, as well as the performance of individuals who conduct or interpret the examinations.

MQSA appropriately placed the responsibility on the facility rather than the individual to ensure that standards which incorporate all elements of the system are met and high quality mammography is demonstrated through accreditation and certification.

Accreditation failure is frequently a

result of a number of problems within the mammography system rather than a problem with a single element of that system. However, just because a certain element is not functioning well in one facility does not mean that it does not function well as part of another facility.

For example, a technologist may be employed at multiple sites. At one site her mammography positioning technique may be sub-optimal but the radiologists are unwilling to accept poor quality positioning and provide feedback to that technologist so that she may improve.

The facilities expectations are high and good quality is provided. However, at another facility where the technologist works, the situation may differ. The radiologist may not have the same high expectations for quality work or may not have a system in place in which to provide feedback to the technologist on her positioning. The quality of work performed at this facility consequently suffers.

I am also very concerned about the possibility of utilizing the medical outcomes audit

data required under the FDA's regulations as a measure of an individual radiologist performance.

The regulations state that, "Each facility shall establish and maintain a mammography medical outcomes audit program to follow up positive mammographic assessments and to correlate pathology results with the interpreting physicians findings. This program shall be designed to ensure the reliability, clarity, and accuracy of the interpretations of mammograms."

The medical audit is intended to be used as a quality assurance took within a facility, not as a performance assessment tool of the facility. Medical outcome audits are fraught with problems that make comparison of results among different facilities and even among physicians within a facility difficult and unreliable.

First, there is the issue of statistics. Many facilities use radiologists employed in large groups similar to mine. The number of patient examinations interpreted by an individual radiologist in a facility may be extremely low, particularly if

you have such specialists such as neuroradiologists or interventional radiologists doing mammography reading.

Although the total number of examinations that the group interprets may be high, outcome audit statistics are inherently unreliable at low numbers. Facilities do not all serve the same patient demographics. Some facilities may only do screening examinations. Some may also perform diagnostic examinations on difficult problem solving patients.

Some may only serve older patients of high risk. Some may cater to a younger population of lower risk. Some may only accept a certain type of payment or insurance that may also skew the risk factors of the population.

Facilities are currently collecting audit data as a part of a peer review process with the promise from the FDA and state inspectors that the information will remain confidential. Without this protection facilities and radiologists could be motivated to avoid difficult cases and in some situations avoid mammography completely.

Due to the lack of common definitions and

public understanding of the statistics, sharing the audit data with others outside the facility may produce undesirable and unwarranted results.

For example, the medical audit could potentially be used as a basis for patients or third-party payers to select mammography providers. Yet, no national database exist in order to provide benchmarks or even comparisons so such decisions would be unjustified.

The ACR has developed a national mammography database program and will begin accepting data later this year with the goal of analyzing in an aggregate manner the success of breast cancer screening and identifying trends and regional variations across differing patient populations.

Ultimately this data will allow us to better understand individual risk and other critical elements of this devastating disease. Submitting data will be voluntary. However, if physicians believe this data will be used to rank them or even eliminate them from interpreting mammography, they will not participate and we will lose the potential benefit

this data provides.

Unfortunately, with the publicity and fear surrounding breast cancer, women's expectations of mammography are unreasonably high. Mammography is the best screening tool available today. But we must keep in mind that 10 to 15 percent of breast cancers will be missed even in the best of circumstances.

Finally, no other area of medicine is scrutinized and regulated the way mammography is. We all believe that this has had a very positive effect on breast cancer detection. In fact, it is only because we are so far out in front of the rest of medicine that we could even consider having this discussion of individual competency.

The ACR will continue to pursue the development of a national database and a self-assessment examination to support the improvement of mammographic interpretation.

If MQSA is used to measure personnel competency, the result could be the closing of mammography facilities. Even under the best of circumstances in a high volume practice like mine

mammography is considered a "lost leader."

This very action could conceivably harm the women this law is intended to benefit by limiting their access to mammography. Thank you.

DR. MONSEES: Thank you. This topic, Dr. Destouet, is on the agenda for right after the lunch hour break. I hope you can stay if the panelists have questions of you at that time and if you would like to add to the discussion.

DR. DESTOUET: Thank you.

DR. MONSEES: Do we have any other members to -- I'm sorry, open discussion at this point?

DR. FINDER: Well, I have two letters that have been received. The people wanted these letters to be read into the public session so let me do that. I'm going to read the bulk of the letters.

The first one is from Dr. Peter Dempsey who is a member of this committee but couldn't make it to this meeting. He writes:

"Since August of 1987 when the American College of Radiology began their voluntary Mammography Accreditation Program, there have been a number of

accreditation programs established relating to mammography, breast ultrasound, stereotactic and other image guided breast biopsy systems.

The only mandatory program, of course, is that relating to having FDA certification of all x-ray mammography sites as required by the MQSA legislation of 1992. All of these programs relate to machines and sites and **NOT** to the **competency** of physicians involved in these procedures.

The growing trend in this country for mandatory recertification of physicians, however, has brought this question into a place of greater focus and interest.

The American Board of Radiology, the American College of Radiology, state medical societies, and now the FDA seem interested and yet perplexed on how this is to be carried out (if at all) for breast imaging.

The organization most interested and indeed best equipped to deal with this question is the American Board of Radiology, the body which grants initial specialty certification for radiologists,

grants certification of additional subspecially competence in certain areas (eg. pediatric radiology), and which now is pondering the overall problem of mandatory, periodic recertification.

Being heavily involved in the American Board of Radiology Oral Board Examination for the past eight years and more recently serving on the FDA NMQAAC, I honestly believe that the last thing the FDA wants to do or should do is to get embroiled in this facet of physician practice.

At this juncture I believe that it would be productive, however, to convene a meeting involving the FDA, the ABR, and the ACR for purposes of mutual education and goal planning in which there would be no duplication of effort or, worse still, working at cross purposes to achieve the ultimate goal which would be a fair and objective measurement of a physician's skill in this very critical area of medical practice.

For example, the ACR and its subsidiary group, the Society of Breast Imaging, have conducted practice competency examinations at many national

meetings and could share this data. The ABR could give the most comprehensive overview of its experience in annual "mass testing" in an objective way with intense, verifiable oversight.

Does the public deserve assurance of competence? Of course, but it is ironic that at present breast imaging is carried out under the weight of the most complicated, costly regulations accompanied by the most draconian penalties for alleged transgressions than the field of cardiac transplantation or any other field of medical practice, for that matter. There is clearly something wrong with this picture!!

Breast imaging is an extremely complex field with differing approaches to seemingly the same problem, all of which may be legitimate. Some physicians may choose to read only "screening" mammograms while others may want to do "screening" as well as "diagnostic."

As the field of MR of the breast progresses, will one have to be a mammographer to read these, or could someone trained in body imaging be

competent as well? These are a few of the vexing questions which must be faced at some point by one or more of the above-named organizations. I say again, however, that in my opinion the FDA should NOT be the certifying body in this area."

The second letter is from Dr. Carl D'Orsi who is Professor and Vice Chairman of Diagnostic Radiology at U. Mass. Memorial. He goes on to say that he couldn't attend the meeting also and:

"There are already many safeguards in place that address competency in mammographic interpretation. All residents who were board certified in radiology for the past ten years had to pass a rigorous written test and oral test which included all facets of mammography.

In addition, this issue is again addressed in the FDA regulations requiring interpreting physicians to read at least 540 mammograms per year and obtain 15 hours of CME credit every three years.

There is also the provision that requires portions of this CME credit to be in any new modality that a physician uses when practicing breast imaging

and interventional procedures. This, of course, is in addition to the other FDA regulations pertaining to technologists and equipment. Certainly mammography is the most regulated area in medicine today.

While it seems attractive to give some sort of "test" to evaluate competency it is not that simple. It is extremely difficult and time consuming to prepare an exam that must be given to a large number of individuals (there are about 20,000 physicians who currently interpret mammography).

This exam must ensure that what is tested relates to quality interpretation which is an extremely daunting task that could easily take years to accomplish. This is especially true if we are using it to exclude physicians from interpreting mammography which is altering their job on an involuntary basis.

I can predict that many physicians would happily not interpret mammography if they were forced to take such an exam even if it was one that was determined to be fair and equitable. The regulations and poor reimbursement for mammography already have

caused individuals to seriously consider abandoning mammography.

Expansion of requirements for the medical audit for both facilities and physicians is also fraught with significant problems. The regulations define at present what should be collected for medical audit. This is basically the PPV-3 for the facility and individual reader.

Even this presents difficulty due to the great variation in mammography practices and the great potential to misinterpret the data. For example, an individual or facility might show a PPV-3 of 50 or 60 percent which means that more than half of the time that individual or facility recommends a surgical biopsy based on a mammographic finding malignancy is found.

While on the surface this may seem to be more desirable than a PPV-3 of 30 percent, this may not be the case. For example, the stage of disease found for the former PPV-3 may be more advanced so only more obvious findings go for biopsy, thus potentially increasing false negative exams.

Or an individual with a high PPV-3 may have only recommended 8-10 cases for biopsy and this number is then meaningless. Remember that the rate of malignancy per 1000 women examined is at most 4-5/1000. One practice might have a predominance of young women with a low prior probability of malignancy which would result in a totally justifiable lower PPV-3 then one that is dealing with a population in their 60's or 70's. These problems outlined above are magnified even more if we regulate false negatives and sensitivity.

It is extremely distressing to me to hear that some individual states are using their states rights' authority to subtly, and perhaps not so subtly, initiate competency requirements.

In these circumstances I strongly feel that the FDA must exercise their right to have states clearly demonstrate a direct connection between interpretive improvement and the additional regulations they require."

Again, we will be discussing this this afternoon.

DR. MONSEES: Thank you. Okay. We are going to move on then to the next agenda item which is FDA oversight of MQSA inspectors and inspections. Would you like to introduce that?

DR. FINDER: Yes. Angela Clingerman from our Inspection Support Branch will be speaking.

DR. MONSEES: Thank you. Good morning.

MS. CLINGERMAN: Good morning. My name is Angie Clingerman from the Inspection Support Branch, Mammography Division.

DR. MONSEES: Can you put the microphone up just a little higher or speak a little louder? Thank you.

MS. CLINGERMAN: My presentation today is about the MQSA Inspector Program. As you may recall, under MQSA, FDA certified inspectors conduct the nearly 10,000 annual inspections of mammography facilities. These inspectors are both FDA and State employees.

Currently, FDA has a trained cadre of 260 inspectors. These include: 216 state inspectors under contract with FDA; 31 FDA inspectors; and 13

inspectors under the States as Certifiers program.

To become a certified MQSA inspector, candidates for inspector training need to meet minimum requirements established by FDA. These include:

A Bachelor's degree in Radiologic Technology, or major in physics, or another major but with at least 30 semester hours of science at the college level.

Two years experience in diagnostic radiology or radiological health work plus certification by the American Registry of Radiologic Technologists, or general or unrestricted State licensure to practice diagnostic radiologic technology, or an Associate's degree in science, or at least two years of college level courses, with at least 16 semester hours in science.

To become certified, a candidate needs to undergo FDA training. This training includes three two-week hands-on training sessions developed by FDA. Course 1 covers the production and properties of radiation, biological effects and measurements and other fundamental concepts in radiation physics.

Course 2 covers the basic patient mammography examination, mammography machines, film processing and quality assurance procedures specific to mammography.

I should also mention that between course 2 and 3 it is recommended that the inspector accompany a certified inspector on 2 mentored inspections.

Course 3 covers the specific protocols that are used by certified State and FDA inspectors performing MQSA inspections. To successfully complete this training, the candidate must receive at least a 70 percent score.

Once a candidate successfully completes the required training and accompanies a certified inspector on two more mentored inspections, FDA certifies them. To maintain their certification, an inspector must: acquire 15 continuing education units within 36 months; perform 24 inspections in a 24-month period; undergo a yearly audit in which an FDA Auditor monitors the inspector's performance during an inspection.

An additional tool used to assess

performance is the evaluation of the inspector's records.

All of the elements that I just presented are packaged under the MQSA Inspector Quality Assurance Program. We initiated this program in 1995 with the primary goal of providing support to our inspectors to ensure that MQSA inspections are of the highest quality.

Secondary goals of the program include complaint resolution, providing continuing education and experience, and obtaining feedback and data from various sources to continually improve FDA's training and inspection programs.

FDA receives periodic information regarding inspector performance from a variety of sources. For example, letters or telephone calls from facilities or other sources; reports from FDA's toll-free facility information telephone line and audits.

DMQRP has an established Standard Operation Procedure to follow up on inspector issues. DMQRP records the issue; contacts the field and the State Program Manager of the FDA Supervisor to discuss

the alleged problem and follows up with written documentation to the group and acknowledges the complainant.

The State Program Contact or FDA Supervisor will investigate and provide DMQRP with written documentation of their findings; consult with the field and DMQRP regarding the appropriate course of action; communicate directly with the inspector, and notify the complainant, DMQRP, and the field in writing about the investigation and proposed resolution.

As I previously mentioned, the primary goal of the Inspector Quality Assurance Program is to support our inspectors. This support includes: The MQSA Inspector Help Desk; Policy Guidance Help System; Mammography web site; all hand e-mails; and MQSA Auditors/Mentors.

I hope my presentation gave you a brief overview of FDA's efforts to select and train a proficient cadre of inspectors and to ensure consistent and quality performance. We would like to hear comments or suggestions from the Committee.

DR. MONSEES: Thank you very much. I think we probably will. I would like to open this for a discussion for the panel. I think this is an important subject and I've heard and experienced myself some unpleasantness during inspection and questions have been raised to me about what type of feedback the FDA gets regarding the conduct of the inspectors, their competency, their willingness to cooperate with the facility, how polite they are, etc.

Recently I've asked what kind of feedback is routinely gained from each inspection. I just sketched in the outline here it seems to me that the only feedback necessarily from a facility is if there is a particular complaint rather than on a routine basis.

I would like to hear opinions, perhaps people who have participated in inspections or heard from people in the community regarding inspections and perhaps some suggestions that the FDA might like to hear regarding what they can do to further improve this process.

Do I have anybody that wants to comment on

this from the panel? Yes, please. When you comment, state your name and then go ahead and comment for the record.

MS. ELLINGSON: Nancy Ellingson. I talk to mammographers on a daily basis. They seem to think we're the clearinghouse for all questions and sometimes I say, "Call the hotline," and they say, "I did." Sometimes they say that we maybe should call you.

There seems to be some question and I have passed this along to Stephanie Bellela at times or whoever I think might be interested only as an informational thing. It may be misinterpreted by the time I get it and I try to pass it on.

Questions that an inspector will say, "I can't accept this continuing education because it's not Category A." I hear that often enough that it may be a misinterpretation because the law, in fact, addresses that, it does not have to be Category A for technologists. Category A and B is a function of ARRT and that is not written into the law.

That is something I hear enough that it

may be, you know, a problem because they call us and say, "I showed them the printout which one of the guidance documents says is an acceptable document and they are not accepting it because that, that, or the other thing." That is something that is a consistent problem and I just wanted to add that.

DR. MONSEES: Are you bringing this up to state that perhaps some of the inspectors are misinformed? Okay. Do the individuals who come to you feel that they know what their recourse is if they feel that they have been incorrectly cited?

MS. ELLINGSON: Well, I generally point out. It actually was addressed by Cathy Akey on the FDA teleconference, this particular question, and that it is written into the guidance that the CMA for physicians must be Category 1 but that CE for technologists only must be documentable but it does not say that it must be approved by one of the agencies to make it Category A.

I thought that was maybe worth mentioning because it comes up fairly often. Not as much as it did at first.

DR. MONSEES: That's a very specific comment. I think what we would like to introduce here is a broader discussion perhaps. This is an important one but I think it gets to one of the important things and that is the inspectors don't always know all of the answers. They do have some support as outlined in this presentation.

The question is do the facilities understand what their recourse is. Do they know how to approach the inspectors. Of course they may feel intimidated about speaking back and rightly so. The state may only have a few inspectors and they can inspect that same inspector in their facility next year.

I think that one of the suggestions that I'd like to make, and I would like to hear panel members, is that there be feedback basically on every inspection.

Since there is already a lot of paperwork in place, I would like to see every single facility given a survey at the end. Maybe they could e-mail it directly in or they could mail it in on every

inspection regarding the competency of the person who was there.

The fairness and whether or not they respected the facility's ability to see patients at the same time and various other issues. I think that would be helpful because I think that being they are only asking for complaints, I don't think they really get full measure of what's going on out there.

Yes. I'll start with Mr. Mobley.

MR. MOBLEY: Thank you. Mike Mobley. I can speak from my experience, particularly in Tennessee.

I think we've had maybe the gamut of inspector issues in terms of having an inspector that has received accolades for her work -- I say an inspector. I probably should say several of them but certainly one of them that I can remember particularly receiving good feedback from a number of facilities -- to having an inspector that, I guess, the best way to characterize was too lenient.

There wasn't a lot of feedback from facilities, as I remember it, when FDA ran the

statistics. And that's going to be a question I want to ask of FDA staff is what kind of statistics do they have on inspector activity?

Because obviously you would expect that if you've got a 30 percent noncompliance rate, and I'm just throwing that number out, that you would find everybody, you know, around that 30 percent noncompliance rate. You wouldn't have somebody at zero and somebody at 60 percent unless there were some real good reasons for that and you would have to look at that.

We've also had the experience of having an FDA inspector/auditor that created some real difficulties in some facilities in Tennessee and that is -- I mean, you're adding another problem when you get to that point. That's been our experience in Tennessee.

The interesting thing as I was sitting here listening to the presentation and thinking about this particular issue and preparing for this meeting is our experience has not been any problems with the technical issues, analysis, or whatever.

It's been more the interface almost on a person-to-person kind of basis, as well as just in the general attitude, I guess you would call it, of the inspectors doing the inspections.

I will reiterate my question. What does the FDA's data on inspectors show? Do we have inspectors that never find items of noncompliance? I'm using my terminology, items of noncompliance. And do we have inspectors that never go to a facility that don't find an item of noncompliance? I would just like to see if they have some data on that. Thank you.

DR. MONSEES: Okay. Can we hear from the FDA on that?

DR. BARR: Yes. Hi. Dr. Helen Barr, Deputy Director of DMQRP. I will address your question in just a moment before we got too far from Dr. Monsees' question. This isn't to say that your idea of feedback on every inspection isn't a very reasonable one, but just for your knowledge we did conduct a facilities satisfaction survey of facilities where just such issues as you raised were addressed.

We just hired a contractor to do that facilities satisfaction survey again under the final regulations inspections because the first time it was done was still under the interim regs. That does get to some of the issues you raised. Not on an inspection-by-inspection basis but it includes the kinds of things that you talked about.

DR. MONSEES: So it's only where a facility has issued a complaint?

DR. BARR: It's a random survey of facilities throughout the country.

DR. FINDER: I think the original one done on the interim regs questioned a 1,000 facilities.

DR. BARR: I believe that's correct.

DR. FINDER: Randomly picked 1,000 facilities and asked them to fill out various forms. Or was that a telephone interview?

DR. BARR: No. As I said, you serve your suggestion but it's just kind of an FYI point.

MS. CLINGERMAN: As far as the inspectors --

DR. MONSEES: Could you state your name? Speak into the microphone.

MS. CLINGERMAN: Oh, I'm sorry. Angie Clingerman. As the noncompliance and the percentages and things like that, we are currently working on a spread sheet to get that information out for all of the inspectors. For last fiscal year actually by state contracts is how we were doing it. Hopefully that will be done in December or January is what we're hoping for.

DR. MONSEES: Will that information be disseminated in any way or will the report be made available to the public or interested parties?

MS. CLINGERMAN: When I was talking to the ORA liaison, what we had thought was to do something with the generic numbers across the regions but not specifically for like each state.

DR. MONSEES: We'll follow up with Mr. Mobley and then we'll move to you.

MR. MOBLEY: I just would comment that I think it's a very valuable management tool. I mean, what do you do in a state when you're doing x-ray

inspections or radioactive material inspections. If you've got an inspector that never finds an item of noncompliance, as a program manager I'll look at that and think there must be a problem here or this individual just really was lucky in going into these facilities.

From my experience that's not the case. There is a problem with that inspector for whatever reason and you just have to evaluate those. It is very true much like what we've heard earlier here relative to radiology, it's very true that you may have some specialized inspectors that go into certain types of facilities and they always find items of noncompliance because they are inspecting the more varied facilities that have larger programs or whatever.

You have to use some knowledge relative to what types of inspections are being done. But in a situation where you have relatively uniform inspections for a very what I would call explicitly defined program, you can expect that your inspectors are going to find relatively the same number of -- I

say relatively the same number.

They are going to be within a certain range of findings at these facilities. Anybody outside that range certainly should be evaluated to some extent. Thank you.

DR. MONSEES: Yes.

DR. MENDELSON: Ellen Mendelson. Taking into account the comments so far, I do think that Dr. Monsees' suggestion of a survey to each facility following the inspection should be returned to FDA anonymously. I think it would be very important. Many of the inspectors who come are recurrent. There are several inspectors for each area and they are known to the facilities.

I think that there is an element of a personal relationship that is developed over the years and to avoid any kind of possibility of an impropriety there in terms of influencing an inspector or any vindictiveness on the part of the inspector for a complaint should be made outside of this loop.

The inspector should be notified if there are complaints about the type of inspection and survey

that they are doing, but there should be no mention of what facility it was. It should be an anonymously returned survey to maintain the appropriate types of relationships.

A second point is that in, for example, the American Board of Radiology each examiner receives a statement of his or own statistics with respect to passage and failure of the candidates. That is set against the overall. It is done on a subspecialty by subspecialty basis so that you can see where you fit in with the rest of the examiners as an aggregate.

The training of radiologists I think we can compare to the preparation of facilities for this inspection. The idea here is not a punitive one. We want to make certain that mammography is done as well as it can be in as many facilities throughout the country as possible and to name a range where an inspector must fall in terms of passing or failing, I think, is going to be very difficult.

There will be a lot of individual variation. There may be areas of the country where geographically an inspector may find only one percent

of facilities in noncompliance for various things. In other areas the mammography may not be as good. I think that we have to be very careful before we start setting objectives and goals.

DR. MONSEES: Thank you. Yes.

DR. IKEDA: Debra Ikeda. I know that in my part of the country we have been inspected many, many times because we have three units and in our area many facilities are unaware of a process to provide feedback to the FDA, although there is a way of providing this information back to the FDA on their inspection.

Many of the facilities in my area because of where I am, we have a lot of mammography facilities. The personnel feel quite intimidated because there are only a couple inspectors that come back every year.

As in human nature they feel intimidated if you say something about the inspector. Then it's possible they could come back and give you a bad rating for the next year. It's just human nature.

It would be reasonable, I think, to

provide perhaps better awareness for the facility that there is a feedback mechanism to FDA for both good and bad experiences.

We do read "Mammography Matters" when it comes out and it helps the facilities in general since we're thinking about the nation, about why facilities fail, what inspectors have found.

I think if there is a feedback mechanism back to FDA, it would be very helpful both to FDA and to improve mammography and their ability to provide good images across the nation.

DR. MONSEES: Yes.

DR. YOUNG: Yes. Don Young. I would like to add my support to the survey. I want to stress that anonymity is a foundation of this survey. The few complaints I've heard have revolved about the timing of the inspection.

I think we have to be very careful that continuity of patient is not disrupted by the inspection. I've always been a strong advocate of examining your examiner and inspecting the inspector.

DR. MONSEES: Dr. Finder, I would like to

ask you if information or survey information were given directly to the FDA, how would that work with feedback to the states? Would the FDA be able to give feedback to the individual inspectors or to the individual states or how would you contemplate something like that would work?

DR. FINDER: Well, we would have to look at all the options but if we have the data, it could probably be given back to the state or inspectors in various different ways depending on how we decide whether it be regions, groups, individuals once we have the data.

Now, when we do have this data whether we get a complaint or a compliment that is given back directly to the inspector. We do investigate all complaints. We don't necessarily investigate all complements but we do investigate the complaints to find out what happened because we do want to get back to the facility with a resolution of their complaint.

If we're talking about general data that we would get maybe back from a survey, that we haven't had in the past for each individual inspector so we

haven't given it back to them. If we do have that data, I'm sure it could be delivered back to them in that manner.

DR. MONSEES: Yes.

MR. PIZZUTIELLO: Bob Pizzutiello. I have had experience with a number of facilities who've had problems with inspections. None of them were aware that they had a procedure or recourse.

They called me and I let them know that they could do that. They contacted folks at FDA and the process went on from there. The first question I think that was raised early on was are facilities aware. I would say in my experience generally not.

Second is in terms of the discussion about a survey, we are all about quality improvement, trying to improve the quality of what each one of us does. There isn't a single department that I've ever been in that has not instituted some sort of a regular ongoing survey of patients coming through the customer focus, if you will, "How are we doing?"

I think this quality improvement focus could clearly be extended to the inspectors. It would

require a little bit of work but it could be seen from a quality improvement perspective, again not a punitive or a critical perspective.

It's a way for the inspectors to learn how they can improve what they do and for the division to be able to do a better job with their inspection program. I see that as a very positive step.

I would again echo the comments other people have said, that the inspector community is small and it absolutely needs to be confidential. Otherwise, people will not be forthcoming with their comments.

I have a different issue I would like to raise, and that is perhaps a bit technical but on a critical issue. It has to do with the training of inspectors in regards to scoring phantom images.

I was recently contacted, in fact, just this week, by a facility that received a Level 1 citation during inspection for a failure of the phantom image on a very subtle issue which has to do with the scoring of masses and artifacts and was the mass round and so on.

In my capacity with the American College of Radiology Mammography Accreditation Program we spend a tremendous amount of time and effort working with the physics reviewers in the accreditation program to try to establish the benchmarks for this particular scoring pattern, as well as all the scoring patterns, and it's notoriously difficult.

We work very hard on that. We have methods of evaluating our scores of different reviewers. We have peer review if there's discordance and so on. I have a concern about a Level 1 violation that is issued by an inspector on a relatively soft issue like this in light of this following comment.

In the early days of inspector training the inspectors were trained in scoring phantom images by a medical physicist who is involved with the accreditation program and who is an expert in scoring. I was one of those. However, it's been several years since any medical physicist with that level of expertise has been involved in the training of inspectors or retraining or evaluating of the program.

I have a bit of a concern that the

inspectors who are out there now may not have benefitted from that kind of expert training. On the particularly subjective or potentially subjective area such as scoring the masses, I think this is an area where the inspection program could use some improvement.

DR. MONSEES: Do you have any suggestions how that could be? Perhaps a double read on some of them submitted or do you have any ideas about what could happen?

MR. PIZZUTIELLO: Yes. I would suggest two things. First, we have a program in the ACR where phantom scores that are discordant where you have two reviewers who disagree are reviewed by a senior reviewer. I think there could be a similar situation at FDA where there would be a senior expert person who reviews phantom image failures at the Level 1 compliance problem.

There are not very many of these so I don't think this would be an overwhelming task. I also think in order to do that there needs to be someone at FDA at that expert level and some ability

to provide training so I would further recommend that someone at FDA receive some really in depth training and that the in depth training from an expert become part of the subsequent inspector training program.

DR. MONSEES: Yes. Any other comments? Go ahead.

MR. MOBLEY: I would just like further comments. I agree that I think the program has to be seen to me as a support activity for inspectors to improve their inspections and their interface with the inspected facilities.

One of the things that we have done in the past in Tennessee is as we evaluate our inspectors activities is every quarter we put out a notice to the inspectors. It just goes out to the inspectors and their management that tells the results of the previous quarter, the numbers of inspections that the inspector did, and the rates of noncompliance found.

It's broken down on dental inspections and different levels of inspections because you expect to find different levels of noncompliance for different types of facilities.

It's sort of a gauge where the inspectors themselves get an opportunity to see where they fall in the line of the rest of the inspectors. If you have, again going with my early example, 30 percent noncompliance and you have one inspector that's finding zero and one inspector that's finding 60 percent, then there's need for understanding why that is.

Sometimes it a matter of the inspector looking at it and saying, "Okay, what is my problem here? What do I need to do?" Obviously to me it's a serious question for the management to evaluate.

In the situations in Tennessee we got feedback from FDA relative to our inspectors, both the ones that got complements as well as the one that apparently had a problem in the inspections they were doing and we worked to resolve those.

From my perspective that's the way it ought to work. As a result of my question, I now know that maybe there's not a full-blown system within FDA to really evaluate the inspectors. I think they should develop that and work toward trying to provide

the information to the inspectors as well as the inspector's management so that we can move on in this arena. Thank you.

DR. MONSEES: Just one second. I just want to say that the report card, so to speak, or the benchmarking really is a better term for it, it's exactly what Dr. Mendelson was saying. It's done for the American Board of Radiology examiners. They look at how they compare to others and I think that you're advocating the same sort of thing.

One of the other components that I would suggest on that benchmarking would be the number or percentage of citations that are overturned upon appeal because I think that would be a good measure of whether somebody is justly citing somebody or not. If that's not tracked, it should certainly be.

Yes.

MS. FRANKE: Hi. I'm Kathy Franke, the Chief of the Inspection Branch who is responsible for the training of the inspectors. I want to thank you for all of your comments. These are the things that we ourselves are reviewing in-house.

I did want to mention that we are currently developing a profile which is an electronic means by which we can capture all the information that we collect relative to an inspector's performance.

When we have that profile developed, we will be able to produce lots of spreadsheets and electronic means of communicating with the states and the inspectors about their performance.

I did want to say that when we have problems with the inspectors, we now keep hard copy files on each and every one of them and we work closely with the food and drug administration's Office of Regulatory Affairs who manages the negotiations and the oversight of the contracts with the states, as well as with the state programs. We also include the inspectors in this investigation of their performance so that they don't feel as if they are being blind-sided in the end.

I did want to say that as far as the phantom imaging scoring is concerned, yes, your comments about reintroducing the idea of bringing in perhaps the ACR to help teach that is a good one. I

will say that we have continuing education in addition to the normal training course that we provide, the phantom imaging scoring skills.

We recently had the video presented at the CRCPD annual meeting this year back in May. In addition to that, we have peer review both from state senior management and other inspectors in states. A lot of times it depends on the culture of the exact state involved.

In addition to that, when there's a question between the state supervisors, the facility, and the inspectors, the FDA gets involved and we try to break the tie somehow. All your comments are well received and we will consider all of them.

I want to reassure you that we are in constant vigilant duty in relationship to both the state contracts, the performance of the inspectors, and the concerns conveyed to us by the facilities.

Stephanie, did you want to add anything on the training?

This is Stephanie Bellela, our training coordinator.

MS. BELLELA: I just wanted to mentioned that --

DR. MONSEES: Could you state your name for the record?

MS. BELLELA: Stephanie Bellela, training coordinator with the FDA. I just wanted to mention that since we have stepped away in training from having experts from the field do specific lectures, which it's not just in phantom image scoring but a lot of other areas, we've moved into staff experts. They have all that have taught the phantom image scoring lecture attended the ACR's course for the physicists in phantom image scoring.

DR. MONSEES: Okay. Ms. Hawkins.

I'm sorry. Were you finished with your comments?

MS. FRANKE: Dr. Mourad has a comment to add. We work as a team here.

DR. MONSEES: You work as a team. Okay.

We'll come to you in a minute.

DR. MOURAD: Wally Mourad, Inspection Support Branch. I would just like to address one

little area in the inspection regarding the phantom images that has not been stated yet. First of all, the inspector has the chance to score two phantom images, not one. If the first one fails for whatever reason, the program prompts the inspector to take another phantom image and score it. That's another assurance.

Furthermore, if a level one phantom image is issued, we typically tell the inspectors that should not be finalized right away. In fact, most of the states, not all of them, take that phantom image at Level 1 and review it in their offices involving several inspectors scoring it individually before a final citation of a Level 1 phantom is issued. It's a very serious issues and we take it very seriously.

DR. MONSEES: Thank you.

I'm sorry. Comment from Mr. Pizzutiello.

MR. PIZZUTIELLO: Bob Pizzutiello. Thanks, Wally. That's very helpful and I was fully aware of that. My concern is with the expertise of the people who are doing the end of the line review. I recognize and I appreciate that there is a system

for other people to consider. In fact, in this case there were two inspectors who looked at it. The problem is that neither of those people are at the level that I would consider to be expert in this particular area, especially because it's challenging to score the masses.

I would also say that having attended a course is helpful but in and of itself is not sufficient to make one an expert in scoring phantoms. One of the things that's very important is the large experience with scoring these.

For example, reviewers for the American College of Radiology Program score many, many phantoms and that is what allows them to develop the expertise to recognize the nuances of how to score these.

That's my concern is that while there are a number of people who looked at them, none of those people, in my opinion, may have the expertise in terms of either training or experience or both to really make that fine line distinction.

If it were a Level 3, I wouldn't be concerned, but a Level 1 citation are rare and serious

and facilities take them very seriously. In terms of this whole quality improvement discussion that we're having about the inspections, that might be an area for some further improvement.

DR. MOURAD: Thank you. I think we are addressing that in the phantom training, as Kathy mentioned, with the video that we have prepared we have tried to address particularly the issue of how you score the masses, as you say. We are going to actually be releasing this video very soon. We are trying to improve on it. Hopefully that will iron out the differences.

DR. MONSEES: Thank you.

Yes.

MS. HAWKINS: Patricia Hawkins, Consumer Representative. I just wanted to say that in this conversation as it relates to feedback of facilities and oversight of inspectors and inspections, I think that we can look in terms of the history of regulations and so forth and proceed with caution.

We do not want to create an environment where basically the industry can intimate the

inspection process because that certainly can happen.

DR. MONSEES: Okay. Any other comments on this? Okay. Do we have any pertinent comments from the audience on this? Okay. Then we're going to move on.

Because we are a bit ahead of schedule here, we can either -- let me confer with my colleague, Dr. Finder, here. We are going to move to take care of some business at the very end of the day now. We can't move up certain subjects for discussion too early because people are expecting to come from the outside perhaps on a certain schedule.

We'll move to the review of the summary minutes of the January 2000 meeting. Those of you who were here will remember that it was quite interesting weather circumstance at the time.

Do we have any comments on those minutes? I would like to hear a motion of approval of the minutes, January 2000.

MR. PIZZUTIELLO: Move to approve the minutes.

DR. MONSEES: Thank you. Second. All

agree? Okay.

Should we discuss future meetings?

DR. FINDER: Well, in terms of future meetings, it actually brings us to the next part which is presentation of awards because a significant number of people on this committee will be finishing their term after this meeting so I really don't want to set up any time for any future meetings because we are going to be having a whole new group of people coming in.

What I'll do is the same thing we've done in the past which is once we have all those people approved send out an announcement to all the members asking for open dates and try and set up a meeting based on that. Judging from our last experience with the January meeting we are going to try and go to a spring/fall meeting schedule rather than a snowstorm/hurricane schedule.

One can count probably on sometime in the spring of 2001 for the next meeting so keep your calendars open for that entire season for the meeting. Again, we will probably be talking about a one to

two-day meeting but you'll get further details at that time.

One other thing that I would like to do at this point is to give the presentation of awards for the people that have served on this committee for the last three or four years. I will be happy to hand out the awards if I can get a pledge from the people that they will agree to come back for the afternoon session, that after we give out the awards that they just won't take it and leave. Knowing the people that I'm going to be handing these out to I have no worry about that.

Let me briefly go over this. We have a plaque and a letter. I'll just read one of the letters as a representative sample. This one is for Dr. Monsees.

"Dear Dr. Monsees, I would like to express my deepest appreciation for your efforts and guidance during your term as a member and chair of the National Mammography Quality Assurance Advisory Committee.

The success of this committee's work reinforces our conviction that responsible regulation

of consumer products depends greatly on the participation and advice of the nongovernmental health community.

In recognition of your distinguished service to the Food and Drug Administration I am pleased to present you with the enclosed certificate." It's signed by Dr. Jane Henney, Commissioner of the Food and Drug Administration.

DR. MONSEES: Very nice. Thank you.

DR. FINDER: We have a plaque we are giving to you, Dr. Monsees, and the others who are leaving. Certificate of appreciation in recognition of distinguished service.

DR. MONSEES: Thank you.

DR. FINDER: I have a similar plaque for Dr. Mendelson, Patricia Hawkins. I'll go to this side again. Mr. Mobley and Mr. Pizzutiello. And we're still ahead of schedule.

DR. MONSEES: Okay. We're going to go to break.

MR. PIZZUTIELLO: Can I make a comment first?

DR. MONSEES: I'm sorry?

DR. FINDER: You don't like your plaque?

MR. PIZZUTIELLO: No. I would just like to make a comment on behalf of all the members of the panel because there have been many discussions and so on to thank Dr. Barbara Monsees for a wonderful job as chair, really. She has brought a level of professionalism and openness to this committee that has been very much appreciated by all.

DR. MONSEES: Thank you very much.

DR. FINDER: I personally would like to second that and express the appreciation of all the members from FDA for what's been going on for the last couple of years. Not only with Dr. Monsees but with this entire committee.

DR. MONSEES: I would like to thank the people with whom I've worked on this panel and the FDA who have made my job much better and easier than I ever thought it would have been. Thank you.

We'll go to break for 20 minutes. When we come back I think we are going to discuss good guidance practices and the draft guidance.

(Whereupon, at 10:14 a.m. off the record until 10:36 a.m.)

DR. MONSEES: Could people please be seated. I would like to reconvene. We're going to move on now to the discussion of the proposed guidance, the draft document that you have. Before we do, Dr. Finder would like to give you some information about good guidance practices. Particularly for those new members of the panel this is important. Thank you.

DR. FINDER: All right. For those -- I won't characterize them as old members but the previous members have been through this guidance discussion before, but for the new ones I would like to give a little brief history on it.

Before we begin our discussion of the proposed final regulation guidance, I would like to briefly explain the procedures that FDA is following as it develops new guidance. In response to public comment regarding the use of guidance documents, FDA held an open public meeting on April 26, 1996.

On February 27, 1997, FDA published a

Federal Register notice outlining the steps the agency needed to take prior to issuing guidance. In brief, it stated the following:

Guidance had to be developed in an open manner that permitted input from the general public and the regulated industry. In most cases new or controversial guidance had to allow for such input prior to its implementation.

While statutes and their associated regulations were binding and enforceable, guidance was to represent a way or ways of meeting the regulations but other ways would be acceptable as long as they met the requirements of the regulations or statute.

I would like to emphasize the following before we begin our discussions. We are here to discuss the proposed guidance, not the underlying regulations. The regulations have already gone through their own extensive approval process and while they are subject to future change, the purpose of today's meeting is to address the proposed guidance.

The documents we will be discussing today contain a mixture of regulations and guidance. When

you see the words "shall", "require," or "must," they refer to the underlying regulation. Whereas the words "should," "may," or "recommend," refer to the guidance.

The committee will be reviewing documents that have already been released for public comment. With that, we can begin our discussions of the document that we have.

DR. MONSEES: Members of the panel, for the draft guidance there was a document sent to you in advance which I hope you reviewed. Today we have a version on our desktops here that has line numbers associated with it, I believe it's the same exact document, so that when we discuss you may have to toggle back and forth here and refer to specific lines.

I don't want to go through every line of this document. Obviously it would be much too time consuming so I'm hoping that what we can do is go through a few pages at a time and ask for specific comments and otherwise, if there are no comments, just move on.

Pertaining to the first part under Certification and Personnel - General, do we have any comments from the panel? Any edits or word changes? I have a couple comments if nobody else does.

Under Certification, lines 20 to 26, I think read awkwardly and I'm not sure. I think that needs some wordsmithing regarding you and your group, etc. I can give you comment back.

Then something that I think might be missing there which I think is important because the wordsmithing I can give you but I just want to comment that I don't think it gives them enough -- I think it should specifically, let's say, indicate that they need to have a lead interpreting physician and auditing physician under this type of circumstance.

It does not indicate that responsibility needs to be there. They should know it obviously but I think we're talking about whose responsibility is what and I think that should be included in there.

In the next paragraph I have some wordsmithing, too, that I'll pass on to you. Do you want to discuss that openly?

DR. FINDER: It's up to you.

DR. MONSEES: Does anybody else have any comments on those particular comments on those particular paragraphs?

DR. FINDER: If it's just some wordsmithing, you can just give it to me later.

DR. MONSEES: I'll just do that then. Okay. How about Personnel - General? Do we have any comments from the panel? If I don't see your hand up, just call out so you can get my attention.

I think the word "student" is another wordsmith, too, on page 2, line 19. It's probably not appropriate because they are not really students.

Radiologic Technologist on the next page, Medical Physicist. Comments?

Okay. Equipment, Medical Records.

DR. FINDER: Page 4 and 5.

DR. MONSEES: Equipment is on page 4 of the newer one and the page changes. They are similar but they are not exactly the same. Equipment. They are not exactly the same.

Medical Records which was old document 6

which is new document top of page 7. Then after that we can move on.

MR. PIZZUTIELLO: I have a comment.

DR. MONSEES: Yes.

MR. PIZZUTIELLO: Bob Pizzutiello. On page 5, line 35.

DR. MONSEES: Page 5. This is the new one.

MR. PIZZUTIELLO: This is under the automatic exposure control description and it has to do with performance testing of the x-ray machine in automatic exposure control mode. This line says that the action limits specified in the regulations be applied to this extended test.

What they are talking about here is that normally we test machine performance at 2, 4, and 6 centimeter thicknesses, but many of us also do more than that because it's important to be able to provide facilities with advice as to how to image the much thicker denser breast.

However, I have a very big experience with this and, in fact, we have recently reviewed 150

surveys of facilities of mammography units and it's very rare out of those 150 facilities that we've looked at that mammography units that meet the requirements for 2, 4, and 6 centimeters also meet the exact same requirements for an 8 centimeter breast that's got a lot of glandular tissue in it.

It's just, I think, too demanding to expect equipment to meet that requirement. I would urge that be eliminated maybe to say that the performance be considered, but to urge that those extended requirements be extended to beyond the 2 to 6 centimeter range, I think, is really a practical impossibility and will generate a tremendous number of failures among physic surveys.

Service engineers come in and they say the machine can't do it. A lot of money gets spent and nothing really gets improved. What we really want the physicist to do is to evaluate it and to help facilities get the most out of their equipment for those extreme circumstances.

DR. MONSEES: Any other comments pertaining to this from panel members?

DR. FINDER: I just want to bring up some points. I mean, we did recognize, and I hope we got it across here, that we are only talking about as a requirement for the 2 to 6 centimeter range. Anything above that was a recommendation.

We did add that if the unit can't meet that action limit, that the thing to do is then develop a technique chart. If you think that is still inappropriate, I mean, we certainly can look at revising this again.

The point here was to try and state that we were only talking as a regulation of the 2 to 6 centimeter range but, recognizing that a lot of facilities deal with patients in the 8 centimeter range, that there at least be some attempt to measure that. If you believe that this doesn't get that across, then we certainly would be interested in hearing some other things.

MR. PIZZUTIELLO: Yes. I agree with the idea completely. When I read this it seemed like the first half of the sentence said we recommend that the limits be applied. Then it says if you cannot meet

these limits, then you can do some other things.

DR. FINDER: Right.

MR. PIZZUTIELLO: The plus or minus .15 after a certain year in the future that I'm not allowed to mention could be very, very complex.

DR. FINDER: We won't discuss that year. Okay.

DR. MONSEES: I have a comment from Dr. Nishikawa.

DR. NISHIKAWA: Actually, I thought this read all right. I interpret it the same way that Dr. Finder interpreted this. I didn't have a problem with that.

Further down on the page on the unnumbered page, the page that has no line numbering, it's the last paragraph.

DR. MONSEES: Excuse me a second. I'm not sure you're picking up in the mic. Can you get a little closer to the mic?

DR. NISHIKAWA: I'm sorry. If you want to use the numbered one, it's on the top of page 6, lines 1, 2, and 3. I got confused because they now refer to

a different section saying that what they discuss up above which are recommendations are now guidance. Perhaps it has to be clear what section that's referring to. Not just the number but what category.

DR. FINDER: Right. What's being discussed here is the fact that, I believe, the guidance that's being given originally talks about doing this test under certain conditions. Whereas the next paragraph on page 6 refers to doing the AEC performance during equipment evaluations.

Those are governed under different regulations. That is highlighted here. It's bolded. Once all this guidance gets put into the policy guidance help system, the computerized system, what will happen is you will be able to click on that and it will automatically take you to the next section which is under equipment evaluations.

When we get to that, there will be the guidance referable to how you do this test under equipment evaluations rather than under the annual survey. It is confusing in a hardcopy kind of situation.

I think it will be a little bit clear when it's actually built into the computerized system. Then we can take a look at what the guidance is for the equipment evaluations if you want to at this point.

DR. NISHIKAWA: That's fine. Actually, all I need to know is that this section is referring to annual inspection and the other one is whatever you called it. What the distinction is is not clear from reading this.

DR. FINDER: Right. We can work on that.

DR. MONSEES: Yes.

MS. ELLINGSON: Nancy Ellingson. Am I allowed to back up?

DR. MONSEES: Sure.

MS. ELLINGSON: Okay. I had a question under Radiologic Technologist.

DR. MONSEES: What page is this of the new document?

MS. ELLINGSON: Page 3. The question is, "I have my ARRT(M)."

DR. MONSEES: For line 21?

MS. ELLINGSON: My notes are on my unlined one.

DR. MONSEES: The question is? I have mine.

MS. ELLINGSON: "Will the certificate be sufficient documentation to show adequate training ..." With ARRT changing the requirements, the clinical requirements have been added, they would have to be qualified as a mammographer before they could get the M so it might change this question.

You have to qualify under the MQSA to do mammography before you can satisfy the clinical requirements before you can apply to take the ARRT exam. They kind of flip-flopped it.

It used to be that ARRT got you in the door but now you can't get in the door until you are qualified as a mammographer. Then you can do your 100 clinical check off list before you take the ARRT. Does that change this question?

DR. MONSEES: We clearly need to do something here.

DR. FINDER: What you just told us is very

useful information. It doesn't necessarily change the answer to this question because we have a lot of people out there who already have the ARRT(M) and this is for them.

What this basically is saying if you show the ARRT(M) certificate, that automatically means that you've had the training in these specialized areas and you don't have to show any additional documentation for that.

However, the fact that the procedures have now changed, which is the first time I'm hearing about this, that now you can't even apply for this until you've already met our qualifications. That's very interesting.

MS. ELLINGSON: Their clinical list is 100 mammograms plus sit with the radiologist for 50 interpretations, plus do quality control, quality assurance procedures, plus participate in or observe these things. You really can't do that until you are qualified to do mammography.

DR. FINDER: Right. And the things you have to keep in mind is that the exams, that at least

we require having performed the 25, are going to be under the direct supervision of a qualified radiologic technologist anyhow so they are not doing them on their own. That wouldn't be a problem. But you are now requiring 100 exams?

MS. ELLINGSON: The ARRT is before you can even take the exam. I'm just saying if you're reaching back to say show me what your training was and you had already taken that in a previous time to April '99, then it's still valid. You can't say you can use that now towards your initial training because you can't get that now until you've had your initial training.

DR. FINDER: Well, again, the initial training could have been done under direct supervision. At least from our standpoint the first 25 had to be done on direct supervision so it's still possible for this all to work out I believe without a problem.

MS. ELLINGSON: Thank you.

DR. FINDER: It is good to know that you've changed your system a little bit.

DR. MONSEES: Do the changes that were made by the ARRT need to be addressed in some other question in here perhaps so that when people are looking in the Policy Help Guidance System they can find it?

DR. FINDER: I want to discuss that with you. I don't know if we need to change anything or whether maybe just putting some helpful hints in here might be useful. We can discuss that.

DR. MONSEES: Okay. Any other comments on those portions? Okay. So we are now, correct me if I'm wrong, as far along as page 7 in the new document which is Medical Records. Any comments on that part?

Next is QC Tests. That's at the bottom of page 8 introducing the new --

DR. NISHIKAWA: Sorry, Barbara.

DR. MONSEES: I'm sorry. I didn't see you.

DR. NISHIKAWA: I have a comment on -- let me find the line number.

DR. MONSEES: This is Dr. Nishikawa.

DR. NISHIKAWA: Sorry. Bob Nishikawa.

Page 8, line 40, talking about digital mammography.

DR. MONSEES: Yes.

DR. NISHIKAWA: I would append to the end of that paragraph "or soft copy if request."

DR. MONSEES: For transferring films?

DR. NISHIKAWA: Yes. So in the future for people reading soft copy. They probably want a soft copy and not a hard copy.

DR. MONSEES: It's not approved yet.

DR. FINDER: The issue and the reason it's written out this way at this point, the soft copy has not been approved by FDA yet. Now, you're right, that when that happens, this will have to be modified.

I will say one thing, though. We have to be careful about how we deal with some of the transfers because I don't want to have the situation occur where a facility can take it unto themselves to say, "Okay. We'll give the patient a soft copy." That's going to be totally useless to the patient.

Most of the transfers that are being sent right now, even when soft copy is approved, I think are still going to be hard copy because the surgeons

are going to need hard copy. They won't have the machines to produce soft copy. The patients are going to need hard copy.

DR. NISHIKAWA: If they can't produce hard copy and they want it, they won't request soft copy. There could be instances where some facility, perhaps academic centers, got some proprietary software that can process the images a certain way that they might prefer to look at it that way.

DR. FINDER: Sure. I think once it gets approved I think we are going to have a new question or modify this one to deal with those situations.

DR. MONSEES: Okay. Now QC Tests unless I missed another comment here. We'll move on to QC Tests. That's page 8, 9 and 10 of the new document, and 11, 12. What do we have, a comment? Here we go. Yes, Mr. Pizzutiello. I knew we were going to get comments from you.

MR. PIZZUTIELLO: Well, it's not a lot. Actually, I have a bunch of other comments. I'll come back to this table later when we get into the small field digital image receptor.

DR. MONSEES: Okay. Which page are you on and which table?

MR. PIZZUTIELLO: This is on page 10.

DR. MONSEES: Okay. Required QC Tests for Facilities.

MR. PIZZUTIELLO: Yes. Under the second dose row, what does the third column mean? Screen-Film Combinations Tested With Each Unit. Under the dose I would like to suggest that we add at the end of that phase, the third column, "One S-F combination using clinical techniques that would be used for the standard breast in contact mode."

Let me explain this. This is for machines that are used only for what are called nonstandard breasts or for magnification work. However, all the dose measurements that are made and referred to in the regulations and, in fact, in all the routine literature refer to the doses in contact mode.

I would like to suggest that the guidance documents say that even if a machine is used in mag mode, that the dose that's used for comparison purposes be the dose in contact mode and that be

explicit because the dose in mag mode will be different and I'm not sure that it would be widely understood how to compare those numbers.

DR. MONSEES: Do people often change the screen-film combination for mag mode as opposed to standard mode which would wildly change the dose during mag mode? I mean, we don't at our facility but I know that in some facilities they have setups where they can switch the entire screen-film combination. Usually it would be faster rather than slower.

MR. PIZZUTIELLO: Bob Pizzutiello. It's not common. It's rare. Out of the 150 places we go only one does it. When they do use that, they use a faster screen-film combination for mag work to compensate for other limitations of their equipment.

If we measured the dose using the faster screen-film combination in the contact mode, we would have a really good handle as to how this compares with their other screen-film combination and I think that's the intent.

DR. MONSEES: Right. Sounds good to me. Did you have any other comments on that page?

MR. PIZZUTIELLO: No.

DR. NISHIKAWA: I have.

DR. MONSEES: Yes, sir.

DR. NISHIKAWA: Bob Nishikawa. Two comments on that page. The next line down, Darkroom Fog. Maybe Bob can comment on this. I don't see the point of testing every type of film for darkroom fog because you're likely to get different measurements from different films.

MR. PIZZUTIELLO: At the present time, no. There has been talk in the scientific community about new screen-film combinations that are sensitive to -- have different spectral sensitivities.

There was one that was about to be introduced by one manufacturer and it turned out not to have been introduced but I know some groups tested it. Because it had a different sensitivity, it would be important to test it.

DR. NISHIKAWA: Okay. That's fine then. Then three lines down, AEC Performance - kVp and Thickness Tracking. It's recommended to only test one screen-film combination but it seems to me that if

different speeds are being used, each film-screen combination should be tested.

DR. MONSEES: Is it going to vary using different --

DR. NISHIKAWA: It could.

DR. MONSEES: It could?

DR. NISHIKAWA: I would think so. I don't have experience with this. I'm asking Bob. Screening for different thicknesses, for example.

MR. PIZZUTIELLO: Bob Pizzutiello. I think that's a good point. I have this one facility that does this and the way I do it is if you are a technologist you use one cassette for one type of imaging and a different cassette for a different type. The end result is that you want the films to be consistent no matter what so when the radiologist looks at the images they all look the same.

It would make sense to clarify that to say that you test each screen-film combination in the mode that it is used so that you would compare, for example, the performance of the AEC with the faster screen-film combination in mag mode with the

performance of the regular screen film combination in all the other modes because that's the way it's clinically used. I agree with that. That's a good observation, Bob.

DR. MONSEES: So what about for reproducibility? You were just commenting on thickness tracking. Right? Wouldn't the same apply to the one above?

MR. PIZZUTIELLO: No, because if the system is reproducible, the reproducibility is not a function of the screen-film combination. It's a function of the electronics of the x-ray machine.

DR. MONSEES: That tests independent.

MR. PIZZUTIELLO: That would be okay.

DR. MONSEES: Okay.

I'm sorry. We have somebody from FDA.

DR. MOURAD: Wall Mourad, FDA. Isn't the purpose of the kVp and thickness tracking to test the AEC as such and, therefore, is not a test of the film-screen combination?

MR. PIZZUTIELLO: Bob Pizzutiello. That's true, but the AEC can be separately adjusted on many

machines so that it can compensate for the fact that you have a different screen film combination when you are using mag mode, for example.

I would say that the purpose of the AEC testing is to show that the machine is capable of producing good images for the radiologists to interpret.

Now, perhaps you could take a different view that in the regulations the AEC is an equipment requirement but I would see that you interpret that in terms of the way it's used clinically. The machines generally can do something to compensate for different screen-film combinations.

DR. MOURAD: Correct. When you set it up, you do set it up for different film-screen combinations but for testing it for its functionality, I don't see why you need to test it for different screen film combinations. That was our thinking in putting out this particular guidance.

MR. PIZZUTIELLO: The point is, for example, and this happened at one of the facilities I went to, they went to using a different screen-film

combination, a faster one for max, but they never changed the automatic exposure control setting so all the mag films came out terribly dark. Well, it didn't really help them.

What I was able to do was to work with the facility and the manufacturer to come up with a combination of changing the settings on the automatic exposure control and their technique chart so that they were able to get consistent images whether they were mag or nonmag.

DR. MOURAD: Okay. I guess we'll have to look at it again.

DR. MONSEES: Okay. We're finished with this table then. Correct? Anybody else have any comments on this table? Let's move on to the next page then. Any comments on that page? This is the daily quality control tests, the weekly quality control tests, and then I'll open it to semi-annual quality control tests. Any comments?

Okay. How about compression device performance? I have a question on this pertaining to line 16, I guess, on page 13, that the fine adjustment

has to maintain compression force for at least 25 pounds for the length of time it takes the radiologic technologist to engage the fine adjustment control.

Then the next line, "for the length of time it usually takes the radiologic technologist to complete an average exposure." That's line 18. Some exposures can -- I mean, most machines are about a max exposure of 4 seconds and we don't generally use them but occasionally you can.

Does it make sense that this requirement applies only to the average exposure and not the maximum exposure time? Because if you have a patient like that, you would want to have that compression for the full exposure time. Wouldn't you?

MR. PIZZUTIELLO: I think that's correct. Take out the average.

DR. MONSEES: So it would be the maximum exposure time. There's another place in the document, I guess under the QC Test - Annual where it's the same thing.

MR. MOBLEY: Also on that same page or the previous where you don't have the fine tuning.

DR. MONSEES: Right.

MR. MOBLEY: Fine adjustment.

DR. MONSEES: I knew it was multiple but I'm getting confused because of the two documents and the pagination.

MR. MOBLEY: I understand. I'm struggling.

DR. MONSEES: Thank you.

DR. FINDER: In terms of the maximum exposure, the maximum clinically used exposure. Right?

DR. MONSEES: Well, there's a certain machine limit.

MR. PIZZUTIELLO: Most machines have a four or five second maximum exposure time.

DR. MONSEES: They're set.

MR. PIZZUTIELLO: Sometimes patients go right up to the backup time if it's a real dense breast.

DR. MONSEES: Right.

MR. MOBLEY: But the point is that -- and when I read this I was thinking that's from the point

that the technician sets the patient up, goes wherever they have to go. I guess most of these machines are kind of a set type of fixture. They go where they have to and initiate the exposure and the exposure is done. It's more than just the exposure time per se.

DR. MONSEES: Right. It should be the time it takes her to get there and then to fully expose the patient.

MR. MOBLEY: Right.

DR. MONSEES: Up to the maximum exposure time and not the average.

Any other comments on the new page 13, 14. Then moving along -- yes, sir?

MR. PIZZUTIELLO: I have a question on -- Bob Pizzutiello -- just above Table 2 on the bottom of page 14. This was a distinction that was drawn between the things that are required during the annual survey.

DR. MONSEES: Are you talking about the regulation part or the answer and question above that?

MR. PIZZUTIELLO: The answer just above that. It starts off, "During the annual physics

survey." I want to make sure that I understand this correctly and perhaps I could get a little clarification from FDA as to how they drew this line.

It seems to me that there are more things in this guidance document that need to be done during the equipment evaluation but not everything is required to be done during the annual survey. I guess I wondered what the reasoning was behind that.

DR. FINDER: Well, I can give you a brief explanation of that. In the regulations the tests that have to be performed for the annual physics survey are defined in the regulations. They are in Part (e), 900.12(e). An equipment evaluation includes those tests plus the test in Part b, 900.12(b).

There are additional tests that have to be included and that's why we are separating those two things out. The number of tests that are required for (e) for the annual survey, as I said, are stated in (e). When you are doing equipment evaluation, it depends on what you do.

If it's part of a major repair, then the issues you would have to address are those specific

issues in (e) and (b) that are impacted by whatever that repair was. That's where the distinction comes between the tests that are required for both of those things. We have to break it down that way.

MR. PIZZUTIELLO: I guess this gets into this line of distinction between what is good professional practice to make sure the facilities are providing quality work and what is stated in the regulation.

I just have a little concern that this statement is too weak and that physicists are always under pressure to work faster, to work for less money, to do less, and so on, as is everyone in this profession.

And that this will cause physicists to not test, for example, the mag mode and automatic exposure control, and so on, during annual surveys. That means it could be tested once when the machine is installed and perhaps never again. Is that really what you think the intent of the annual survey is?

DR. FINDER: Well, I would say, again, we are here to discuss the guidance, not the underlying

reg. The reg went through the process and some of these issues were discussed at that time as to what's required to do in an annual survey versus what's required to do when the equipment first comes on line or if there's been major repairs done to it.

Obviously we want people to do the best job that they can or set a baseline minimum for what they have to do. We have to be very careful about putting things into guidance. That's how we ended up in this whole guidance procedure is we cannot through guidance require something that isn't require in the regulation.

You have to be very clear about that. These documents have to go through a legal process so that we don't overstep our bounds in terms of this because we cannot just generate new regulations through guidance. Now, if you think that we need to change the regulation, that's a whole other issue.

DR. MONSEES: On the other hand, you could indicate in the guidance that this isn't required but that the physicist might attend to that during their normal course of inspection. Right? Could you do

that?

MR. PIZZUTIELLO: Yes.

DR. FINDER: We could certainly recommend things and suggest things. No problem with that.

MR. PIZZUTIELLO: And I guess maybe that's what I'm suggesting is just a little bit more phraseology that says "while not required it is recommended."

DR. FINDER: Sure.

DR. MONSEES: Okay. Any other comments on that? We'll move on then. If you see anything else noted, we can certainly go back to that. We're on page 14 now. Then the top of 15 which is that other table, Table 2. Then we move on to the Medical Physicist's Annual Survey at the bottom of page 15. I don't see any hands up so we'll keep going to mammography equipment evaluations question, page 16, then page 17. Then we'll move on to the table on page 18.

MR. PIZZUTIELLO: Bob Pizzutiello. I have just one comment on the equipment evaluation. The first answer, this has to do with --

DR. MONSEES: What page are we on now?

MR. PIZZUTIELLO: This is on page 16. Sorry. The answer says, "At a minimum, the following tests must be done for a processor that has been replaced, undergone major changes," and so on.

DR. MONSEES: Okay.

MR. PIZZUTIELLO: At the end of that discussion it says, "If major repairs or the use of the new processor necessitates a change in clinical technique factors (for the standard breast) that could significantly increase patient dose, a determination of dose must be done."

I have a little concern that could significantly increase patient dose is going to be very difficult to determine what is significant and what is good. I would just like to say take it out to say that if it necessitates a change in clinical techniques factors, a determination of dose must be done. Then you remove the ambiguity is it significant and if the dose changes, I think it's important that a facility knows that.

DR. MONSEES: So if routine change in

clinical technique factors.

MR. PIZZUTIELLO: Yes. I guess if anybody is not comfortable with that, then maybe we could say something like a change that might affect the dose by more than 10 percent or something but let's say what that change would be rather than significant. I think that's too vague.

DR. MONSEES: I'm just a little confused as to what role, for example, the maintenance people would have if they came in and changed phototimer settings or made similar changes in the equipment that would allow somebody to use the same technique factors but, in fact, would change the dose as well.

MR. PIZZUTIELLO: The way I understand it, this only is if a processor is replaced, undergone major repairs, or is a new processor. It's a situation where you have a major change.

DR. MONSEES: Right.

MR. PIZZUTIELLO: In that case, the physicist is already there doing a number of things and I think the question is is it important or is it important that the physicist among those things test

the dose if the clinical technique factors change.

DR. MONSEES: Gotcha.

MR. PIZZUTIELLO: I would say yes.

DR. MONSEES: Okay. I think that's probably appropriate.

Do you have any comments as a physicist here?

DR. NISHIKAWA: I concur with that.

DR. MONSEES: Okay.

MR. MOBLEY: I concur, too.

DR. MONSEES: Okay. That's the panel's consensus here.

DR. FINDER: All right. So am I understanding correctly that if there is any change that theoretically could cause an increased dose, you want the physicist to come out and repeat the dose measurements even if the facility has done a relatively minor change and their dose limits or their dose before was relatively, you know, low to begin with.

MR. PIZZUTIELLO: No, that's not what the sentence says.

DR. MONSEES: The context of the question is major repairs or new processor.

DR. FINDER: Right.

MR. PIZZUTIELLO: So only for major repairs or new processor. I would not extend that to the circumstance you just described because that's a minor change.

If there's a major change to the entire processor and the physicist already has to be there because there's a major change, then I think that the dose measurement is one of the things that should be done.

DR. MONSEES: So we were past that or asking for comments past that and including the medical physicist's involvement in equipment repairs so let's look at that. Do we need to change anything in this table pertaining to the comments?

The processor comments here are minor ones. Aren't they? Installation and reassembly. Maybe in those lines on that table should indicate that the dose needs to be measured? Do you see where it says "processor installation reassembly?"

DR. FINDER: It's page 19.

DR. MONSEES: 18 and 19.

DR. FINDER: Right. But the one with the processor is on page 18 in the middle of that group.

DR. MONSEES: It's 19 on the new document.

DR. FINDER: Excuse me, 19. Right.

DR. MONSEES: We're saying anyway, as Mr. Pizzutiello was saying, that the physicist conducts evaluation in person on both of those, installation and reassembly. Therefore, should we add in there the dose needs to be measured just in the table?

DR. FINDER: Just form my own standpoint I wouldn't do that because then we would have to put it in for all the others issues where it is. The idea, I guess, is to deal with it in the individual question that is before.

One of the points with these guidance documents is that no one question or table or anything else is going to answer all the questions. If we try and shovel all that information into one table, I think it's going to get too big.

DR. MONSEES: Okay. That sounds good.

MR. PIZZUTIELLO: I have a comment. Let's see. It's on the bottom of page 17 on the original document and it's between page 17 and 18 on the numbered pages and it has to do with this. I support the concept of medical physics oversight and --

DR. MONSEES: I'm sorry. I'm lost.

MR. PIZZUTIELLO: It says the facility should consult with the medical physicist.

DR. MONSEES: I'm sorry. I lost you. On the bottom of page --

MR. PIZZUTIELLO: The newest document with all the page numbers it's at the very bottom of 17 and runs over to page 18. On the top of page 18 it says, "By medical physicist oversight, we mean that the medical physicist should be consulted as to whether an on-site visit is required or if other personnel can verify that the standards are met..."

My question is is a facility required to do what the medical physicist recommended. Let me paint a very typical scenario. A facility calls up and says, "What is required?" Under this I would say, "You are required to consult with me as your medical

physicist and I think that for such and such reasons in your case it's important that a physicist come out."

The facility then would say to me, "Well, I've consulted with you but is it required that I do what you say?" I think the answer is probably no but I would suggest that maybe a line be inserted in there that says that the FDA strongly recommends that facilities follow the recommendations of their medical physicists. It sounds incredibly obvious.

However, in facilities where the bottom line is the driving factor and the letter of the regulation, that sort of a statement would give a medical physicist a little more support. I don't know how you can do that but it would be a recommendation.

DR. MONSEES: What would happen, Dr. Finder, if there is a letter in the QA records from the physicist to the facility that says they are recommending something at the time of FDA inspection. If the facility has not met the recommendations or address the recommendations in the corrective actions or whatever, they would be cited, wouldn't they?

DR. FINDER: Recommendations are recommendations. Regulation is regulation. Part of this comes down to the fact that when certain things occur, the medical physicist has to appear on site. That's in the regulations. When a major repair does not occur, then there is no regulation regarding that and a lot of this is designed again as a recommendation to the facility on what to do but it's a recommendation. I mean, we could change the wording here to say something like the medical physicist should be consulted and listened to or heeded or whatever.

DR. MONSEES: R E S P E C T.

DR. FINDER: Yes, something like that.

MR. PIZZUTIELLO: That would be monumental.

DR. FINDER: But we have other situations where the physicist may recommend something that is not in the regulations whatsoever. In that case the facility doesn't have to do it because it's not required. It may be a good idea but we can't require that.

DR. MONSEES: So they would be cited if it pertained to a requirement that they had to meet and if they were outside and they needed to have resolution of their corrective action or whatever.

MR. PIZZUTIELLO: I have two more comments. Different ones.

DR. MONSEES: Okay.

MR. PIZZUTIELLO: I'll be brief. Just before the table there's an issue about the verification, the table that talks about medical physicist involved in equipment repairs.

A question that I think might be good to address directly is is it permissible for a service engineer to verify their own repair? Or when you use the term verify, are you implying that this is a different person that verifies?

DR. FINDER: The implication was not that necessarily a different person had to come and verify.

MR. PIZZUTIELLO: Okay. It might be good to clarify that.

DR. FINDER: That the same person could verify his own work?

MR. PIZZUTIELLO: Right. The documentation of a completed repair, for example, would constitute acceptable verification.

DR. FINDER: What was that wording again?

DR. MONSEES: Documentation.

MR. PIZZUTIELLO: Documentation of a completed repair would constitute acceptable verification.

Then another -- I guess my last question on this table, or almost, is about a couple of areas where I think medical physicist oversight --

DR. FINDER: Let me go back to that.

MR. PIZZUTIELLO: Sure.

DR. FINDER: Are you saying that if the person gave the facility a form that said, "I did the repairs but didn't do the testing again," that would be acceptable? I mean, what's implied here -- not what's implied but what it says is that the test has to be done again. Some test has to be done.

MR. PIZZUTIELLO: That's the question I asked up front. Let me paint a very specific example, a very simple one. A physicist is doing a survey and

finds that the kVps are inaccurate beyond the permissible variation.

The service engineer comes in and recalibrates the unit. Does verification mean that the service engineer's report that says it's okay is enough or does verification mean that the test must be performed again?

DR. FINDER: Some type of testing, not just that the repair was not; i.e., I went in and did something and then I'm assuming that the problem has been taken care of. No. There has to be some type of test that shows that the original problem has been now corrected.

MR. PIZZUTIELLO: Okay. And since this is a test that's listed as a medical physicist tests, the individual who does the test must be a qualified medical physicist?

DR. FINDER: No, because unless it's a major repair and the medical physicist doesn't have to come out, then it goes under the oversight if it's a minor thing.

MR. PIZZUTIELLO: Okay.

DR. FINDER: In which case, again, we are telling the facility, "We are recommending that you consult with your medical physicist."

DR. MONSEES: So with what you're saying, Dr. Finder, I don't see where there's going to be a change in this verbiage at all.

DR. FINDER: Well, maybe not.

MR. PIZZUTIELLO: So for kVp internal adjustment, which is the example I gave, it's listed as medical physics oversight.

DR. FINDER: Right.

MR. PIZZUTIELLO: So that means after the service engineer is finished, then it is recommended but not required that the physicist verify by performing that kVp test again within 30 days. Is that the way you understand that?

DR. FINDER: Or that the medical physicist consult with the repair person to do the test or that he checks what the repair person did over the phone and make sure that things are done appropriately. That's a decision that the physicist makes in consultation. That's the way we're hoping it's going

to work.

MR. PIZZUTIELLO: Because it's oversight as opposed to conducts evaluation in person.

DR. FINDER: Exactly.

MR. PIZZUTIELLO: Thank you. That's very good. The last comment that I have in this regard --

MR. MOBLEY: Mike Mobley. I just want to make sure I understand and that it's clear what you all just arrived at there because the statement is some form of verification testing must be included.

Does that statement need to be a little bit more explicitly defined as to when the medical physicist may need to be directly involved or onsite versus when the equipment technician can make that change?

It would seem to me that it needs to be. Given your discussion, the question and your discussion of it, that there needs to be a further statement that clarifies exactly what this verification is.

I mean, I think that the question and the discussion you had clarified it in my mind. I think

that it needs to be a little bit clearer here so that you can understand. Anybody reading this in the future would understand exactly what level of verification is necessary for which process.

DR. FINDER: I think we can work on clarifying that in terms of who has to do it and under what conditions.

MR. MOBLEY: Right.

DR. MONSEES: And the table complements that in that it indicates certain problem areas and what the responsibility is.

Yes.

MS. ELLINGSON: I just have one question. Nancy Ellingson. Is there any paperwork documentation of conversations between a facility asking for recommendation, a physicist recommending something so that at annual inspection it's available for that inspector to see how many times things were recommended at the follow-up?

DR. MONSEES: What's required, Dr. Finder? Our facility they note everything but I'm not sure that's required unless it is -- unless something did

not meet the regs, right?

DR. FINDER: Right. If it's a major repair or there was a test that is required, that has to be documented and then has to be worked out. When we recommend something, obviously we recommend it. If they decide not to do it, they can't necessarily be cited for doing something that's recommended but not required.

DR. MONSEES: Yes, sir.

MR. PIZZUTIELLO: Bob Pizzutiello. On the last item on the table on page 18 says, "Film type change." The involvement isn't specified. Is medical physicist involvement optional?

I would like to suggest that be changed to oversight for this reason. I think that the medical physicist needs to be involved whenever the dose or the image quality can substantially be changed. Changing the type of film is, I think, one of those circumstances.

For example, if a cassette is replaced and you use a different screen speed up above, it says that medical physicist oversight is involved and I

agree with that. I think that if the film type is changed, the exact same changes can occur and I would recommend that medical physicist oversight replace what's currently written which says medical physicist involvement optional.

Similarly, on the following page under processor, when new operating levels are established, that is very frequently in my experience a time when dose in particular will change and will go up. Rather than have medical physicist involvement optional when new operating levels are established, I would like to see it say medical physicist oversight.

There are two instances under processor where that occurs. One is in the second row where it says "chemistry type" leading to new operating levels. One is the next to last one, "replenishment adjustment leading to new operating levels."

In other words, if the operating levels are changed, then the document would recommend that you at least consult with your medical physicist.

The last comment is under X-ray Unit where it says, "High voltage generator replacement. Medical

physicist conducts evaluation in person." I think that is exactly correct.

Right above it, though, it says, "High voltage generator adjustment." I'm not sure I understand what that means and how that's different from kVp internal adjustment where it's oversight. I would suggest deleting that entire row.

If you replace the whole voltage transformer or high voltage system, then the physicist comes in person. Anything else I would consider to be an internal adjustment and medical physicist oversight would be sufficient.

DR. FINDER: So let me -- for the high voltage generator adjustment you would suggest oversight instead of in person. Is that correct?

MR. PIZZUTIELLO: Yes.

DR. FINDER: Okay.

DR. MONSEES: Okay. Are there text changes that accompanied these recommendations of changing from involvement optional to oversight that we need to go back and take a look at?

DR. FINDER: No.

DR. MONSEES: I thought there was one about operating levels.

DR. FINDER: Maybe you're right.

DR. MONSEES: Isn't there one?

DR. FINDER: I wouldn't swear by it but I think it's in a different section.

MR. PIZZUTIELLO: I think I have that noted somewhere else. You're right. It is mentioned somewhere.

DR. MONSEES: I remember reading it but maybe it's in the policy guidance system. That's where it is. That's something that's already been through the system. We may have to go back and make some changes on that. Okay. We'll do that in a minute then because we're almost done with this.

MR. MOBLEY: I have a question while we're on this table.

DR. MONSEES: Yes.

MR. MOBLEY: It's under the collimator section. For collimator replacement the medical --

DR. MONSEES: What page are we on? I'm sorry.

MR. MOBLEY: The same table.

DR. MONSEES: What same table?

MR. MOBLEY: 18 on the --

DR. MONSEES: Collimator. Yes. Okay.

MR. MOBLEY: For replacement it says, Medical physicist conducts evaluation in person." For adjustment it just says, "Medical physicist oversight." I guess I would like maybe Bob to comment on that a little bit. Does he feel like that's appropriate?

My perspective or history is the adjustment of collimators, we have seen some real difficulties in service personnel being able to do that. At least some service personnel being able to do that adequately. I guess it's a judgment call so I'm asking Bob to give us some feedback.

MR. PIZZUTIELLO: Bob Pizzutiello. I think that the adjustment of collimators can be a tricky thing to do but it's not very tricky to know if the adjustment was successful or not. The reason why I think oversight is appropriate is that after the collimation adjustment is made, the service engineer

consults with the medical physicist. The medical physicist would typically say, "Follow this test, shoot the films, and send them to me and I'll look at them." It's very obvious if the test has past or failed.

Add to that the fact that if it's off by a little bit, there is not a serious consequence to the patient. So it's one area where even if it needs to be tried one more time to improve it, there's no serious consequence to the patient. I think it's okay with oversight. Thank you.

DR. MONSEES: Okay. Any other comments on this table? All right. We have left Infection Control and Medical Outcomes Audit.

DR. YOUNG: I had a comment. Don Young. I wondered when we talk about blood and potentially infectious material, we are to document cleansing of the unit. I wonder about the wisdom of including the cleansing method used and document the use of any specific anti-microbial agents. I had some anecdotal experience where that would have been important to have been in the documentation.

DR. MONSEES: This is something that has been discussed numerous times on the panel and with public speakers, etc. It's my recollection that we usually say according to the manufacturer's recommendations or policies that are in place in the facility or in the state. Do you want to comment on that, Charles?

DR. FINDER: I think in the regulation itself it does talk about what has to be stated as part of the SOP that they do so that they don't have to necessarily each time they do it restate what they've done as long as it's in their SOP of what they are going to do so, yes.

DR. YOUNG: That was the thrust, I believe.

DR. FINDER: I think that's kind of covered already. I think the major point here is to bring out the point about the difference between just general cleaning between patients and those conditions in which there is contamination with blood or potentially infectious materials.

DR. MONSEES: In which case each time it

has to be documented.

DR. FINDER: Correct. In that case it has to be documented. You would be looking at procedures that could be more involved than the ones that are used just between regular patients.

DR. MONSEES: Okay. So the last part is the Medical Outcomes Audit. Do I have any comments there or any others in this entire document? Go back and look through your pages if you would, please, and see if you have any annotations before we complete our comments on this.

MR. MOBLEY: Mike Mobley.

DR. MONSEES: Yes.

MR. MOBLEY: Much as we discussed earlier regarding inspector outcomes and as was mentioned in our public comment period, we talk about the medical audit outcome, medical outcome audit. It would seem like if we are requiring this data to be kept and it would seem that the data could be useful in terms of evaluating the process.

I understand it's a sensitive, or maybe more sensitive than the inspector information, but it

just seems like it would be a very useful thing to have this data collected and evaluated so that we could understand are we improving the medical outcomes with this process.

Do we have grossly varying outcomes across the country and, if we do, can we explain it or does that mean we need to focus on a particular area to deal with whatever problem could be found?

I guess I'm saying it seems like we are requiring this data to be kept at the local level but we're not doing anything with it beyond that. It would seem like it would be very useful or could be useful information.

DR. MONSEES: I think this pertains to the comments that Dr. Destouet, that the two letters that were sent commented upon.

MR. MOBLEY: Right.

DR. MONSEES: I think it will be dealt with in the discussion this afternoon regarding personnel competency. I would like to have the discussion of this at that time. I think there are some compelling reasons why it's difficult to look at

data and make any sense of it. Let's hold that discussion for when we discuss personnel competency.

I just have one other question. Is Pam Wilcox-Buchalla here or is there somebody to talk about --

Is there a table in the ACR manual that perhaps facilities are referring to? I can't remember, Ms. Buchalla, regarding the medical physicist involvement in equipment repairs? Maybe Ms. Butler can comment from the ACR.

Is there something about the involvement of when the physicist should come out? Is there a table like that in the ACR manual, the new quality control manual? Would it be consistent with this? Is it something that facilities need to be notified about or anything?

MS. BUTLER: This is Penny Butler, Director of the Breast Imaging Accreditation Program at ACR. There is a table in the QC manual which is basically a summary of the equipment MQSA requires for mammography equipment evaluation.

However, we don't have a table like the

one that has been discussed here for when the physicist does come out. I think that table is a good supplement to the information we do have in the manual.

DR. MONSEES: So there's no disparity between the current manual that's out there for distribution and people are looking at and what is going to be in guidance?

MS. BUTLER: Not that I'm aware of at this time.

DR. MONSEES: Okay. That's what I just wanted to check to make sure people weren't getting mixed messages. Thank you.

We do want to try and break before noon if we can for lunch so that people can check out so we may need to carry this over. If we don't finish this before lunch we will continue afterwards. I do want to address the modification of the Policy Guidance Help System. This was the other document that you received in advance of the meeting, Mammography Quality Standards Act Final Regulations and Modifications to Policy Guidance Help System #1.

The Policy Help Guidance System is excellent and I really think it's a wonderful resource for facilities. Those of you who aren't familiar with this should take a look. It really is excellent.

So there are some changes that have been implemented and I think that one of the things we discussed is in here. Let's quickly look through this. Does anybody have any comments on these changes that probably are already on the web, right?

DR. FINDER: Yes.

DR. MONSEES: They're already there. Not to say that they couldn't be fixed.

DR. FINDER: Let me just give a little brief history on this for the people who aren't aware of how the guidance process works. Guidance is developed within the division. It goes out either as a proposal if it's a "Level 1" type of guidance indicating that it's new or controversial. Or it can go out as Level 2 guidance those things that are relatively minor changes.

Once these things go out as being official they are incorporated into our policy guidance help

system which is a computerized, for want of a better term, search engine in which you can find all the guidance related to various topics.

That has been populated over the years with the guidance that we've issued but as time goes on we noticed that there is a need to update or change some of the guidance and this document is an attempt to do that.

We basically refer to the actual question that appears in the policy guidance help system. We give the old question as it was written and the change that occurred so that people are aware of what has been changed.

DR. MONSEES: That's good. So you can access this document on the web site or, if you download the newest version of the Policy Help Guidance System, this will already have been incorporated.

On page 16 and 17 this is the new operating level. Did you want to look through that and see whether this --

MR. PIZZUTIELLO: I already have this

marked. It's Bob Pizzutiello. On the bottom of page 16 where it talks about establishment of new operating levels, I would suggest that the phrase we inserted that says, "Due to the complexities associated with reestablishing operating levels that medical physicist oversight should accompany change of operating levels.

DR. MONSEES: So on page 17 where it says, "FDA recommends the facility consult," that's where you're going to put it, right?

MR. PIZZUTIELLO: Yes.

DR. MONSEES: I know. That's why I'm telling you. It's on a different part. Otherwise you would have conflicting recommendations of the FDA. FDA recommends the facility consult with their medical physicist.

MR. PIZZUTIELLO: That essentially is what medical physicist oversight means.

DR. MONSEES: But should we use the word oversight?

MR. PIZZUTIELLO: I would like to use the word oversight.

DR. MONSEES: If that's the term that's

used in the table, I think it's appropriate to be reflected in this text.

Are there any other comments about this Policy Help Guidance Update? Yes, sir. I'll get you in a minute.

DR. NISHIKAWA: Bob Nishikawa. On page 10 when they talk about education requirements for the medical physicist, this is four lines down in the answer. It says, "You'll need to demonstrate that you've acquired some credits in digital mammography..." Why does it say some? The other sections, the techs and the radiologists have six.

DR. FINDER: It comes down again to the regulations. In the regulations for the radiologic technologist and the interpreting physician, it specifically states six CMEs. Whereas for the medical physicist there is no specific number stated.

It just says that you have to obtain credits in this. That's why we couldn't -- well, we certainly could recommend but we couldn't require a specific number because it's not in the regulation.

DR. MONSEES: I had a question about that

regarding whether it makes sense that somebody could act as a medical physicist for a facility that has acquired digital equipment if they, in fact, don't have the experience. It seems to me that the facility would look to those people to have some knowledge.

DR. FINDER: Well, first, we're talking here about the continuing requirement.

DR. MONSEES: Right.

DR. FINDER: The initial requirement is set. They do have to meet the eight hours so they will all have their initial training met before they can provide services for full-field digital.

The issue comes down in terms of the continuing requirement. If we're talking about setting a specific number, we would have to go in and change the regulation again.

DR. MONSEES: Okay. Yes?

DR. NISHIKAWA: I would urge you to consider changing the regulations, particularly because digitals is going to be continuing changing. If you're not up to date, you're not going to be doing your job.

DR. MONSEES: Yes. We may be addressing this this afternoon but go ahead, please.

DR. CHAKRABARTI: Kish Chakrabarti. Since I wrote the regulation, I want to clarify a little bit. The regulation was written on the basis of screen-film system and a lot of physicists said that they are already working on digital system and they are getting experience. Why can't they not use that continuing education unit to apply to screen-film system.

At that time the committee thought that's a good idea. If when we talk about digital we exclude any continuation that is at work to screen-film system, then we certainly need to discuss.

DR. MONSEES: Thank you. I'll go back to you. Did you have a comment?

MR. MOBLEY: Yes. I've got two comments. Page 17. The question is the facilities that have closed but are still certified. The last statement in that section states, "FDA -- wait a minute. I'm lost.

DR. MONSEES: What section are we talking about?

MR. MOBLEY: I'm lost. I'm lost. Sorry. The last statement.

DR. FINDER: Which page?

MR. MOBLEY: Page 16. I've confused myself. Let me start over. We're talking about closed facilities. It states there, "Upon receiving this information DMQRP will work with the ACR and State Accreditation bodies to verify whether a facility is no longer performing mammography.

DMQRP will then delete the facility certification once their accreditation body has updated their database. It would seem like if a facility is closed and you've gotten that information, that you would terminate their certification period and not wait on their accreditation body.

What it says is you're not going -- even if they're closed you're not going to terminate their certification until their accreditation body says to terminate their certification.

DR. FINDER: This is a procedure that has to go through our databases or link to theirs. We get data from them. Party of the issue here is the

confirmation that a facility is closed. We've had discussions with the various ADs about this.

It is not impossible for us to hear from somebody that a facility is "closed" when it really isn't. It may not be operating over a certain period of time and the tech may think it's closed or the inspector may think it's closed but the facility is actually planning on reopening at some point so there has to be an investigation that goes to confirm that this facility actually is closed.

We have had discussions, especially with the American College of Radiology about setting up procedures to deal with it. The way we've come about this is to say the accreditation body will take the lead on confirming the closure of the facility. Once they confirm it, they will put it in their database. It automatically then is sent to us and that starts the process.

If we do it the other way, it becomes more confusing so it's just a method that we've developed to deal with this. I don't think it practically makes a difference. If a facility is closed, they will get

their accreditation terminated and their certificate terminated but it's just a matter of the procedures that we use. That's all.

DR. MONSEES: Did you have a second comment?

MR. MOBLEY: Yes, but it's on a different area.

DR. MONSEES: Okay. Do you have a comment on this particular area? All right. I think we're getting perilously close to 12:00 and people want to check out. We are going end up discussing this --

You want to make a quick comment? Go ahead.

DR. MENDELSON: Ellen Mendelson. With respect to the specific credits for imaging modalities, I think that the ACGME as the accrediting body of continuing medical education courses should just be notified that it would be a good guidance for them to notify program directors to organize the material for breast imaging with specific annotation as to what credits are appropriate to what. That's the agency of the AMA, the ACGME.

MR. MOBLEY: I've personally spoken with them. It's a process that has to --

DR. MENDELSON: It goes.

MR. MOBLEY: Yes.

DR. MONSEES: Okay. How about if we break for lunch and then we'll take additional comments and have additional discussion on this particular document which we are not yet finished with. How much time do we want? Let's see here. It's 10 to 1:00. How about if we're back -- I'm sorry, it's 10 to 12:00. How about if we're back at 1:00. Does that sound good? See you then.

(Whereupon, off the record for lunch at 11:50 a.m. to reconvene at 1:00 p.m.)

A-F-T-E-R-N-O-O-N S-E-S-S-I-O-N

(1:06 p.m.)

DR. MONSEES: Good afternoon. I think we'll get started. We're going to continue now with the discussion about the modifications to the Policy Guidance Help System. I know that there were some additional comments.

We left off with you and I think you wanted to make another comment.

MR. MOBLEY: Yes. Mike Mobley. This is a comment. It's page 17 on the original document we had. It's in the section, "Reestablishing Processor Operating Levels Over the Five-Day Period." The last sentence, "FDA recommends that during the five-day averaging period, the facility daily perform and evaluate a phantom image as a means of monitoring image quality."

I just felt like -- and I guess the answer to this is it's not in the regulations. I just felt like that was really a thing that should be done just as a routine and that just recommending it seems like we're saying, "FDA is saying we recommend you do

this."

It doesn't get the real thrust that I think it probably deserves. I don't know that you can do anything. I just felt like it needed a stronger recommendation. Maybe "strongly recommend." Thank you.

DR. MONSEES: What do you think, Charlie? Is there a stronger way to word that?

DR. FINDER: We can certainly look at it.

DR. MONSEES: Okay. How about any other comments on the modifications? That was a short one. We could have done it before lunch. So we are done with this document?

MR. MOBLEY: That's it.

DR. MONSEES: Any other further comments anybody mulled over the draft guidance that we did before? Any other last changes to that that you thought about during lunch on the panel? Okay. Then I think we are going to move on to the next topic which is one that we touched on this morning several times. We'll be starting to hear first from Dr. Finder on the FDA's role in evaluating personnel

competency.

DR. FINDER: Before the committee begins discussion I would like to give some background information to place the matter of personnel competency in context.

Under MQSA FDA has authority over mammography facilities, not the individual personnel within the facility. For example, when a person is found not to have met one of the personnel requirements, the facility, not the person, is held responsible and is cited.

In addition, once a person meets the qualifications as specified in the regulations, he or she is considered qualified to provide mammography services to a facility. There is no other regulatory mechanism to judge the competency of personnel providing mammography services once they have demonstrated that they met the requirements.

When the interim and later the final regulations were being developed, FDA considered two different mechanisms for determining when a facility could use a person to provide mammography services.

The first was to require certain levels of specific mammography training and experience which would give a reasonable assurance that the person was competent to provide mammography services.

The second was to require that personnel pass some form of competency test. These two approaches were discussed with the original members of this committee as well as put out for public comment.

The majority of comments that FDA received on this issue were opposed to the implementation of competency testing as part of the regulations. Reasons given included that no competency test existed and that the current requirements were adequate.

It was also suggested at the time that medical audit data could be used as a measure of physician or personnel competency. Both the NMQAAC and most of the public commentors stated that it was inappropriate to require the collection or release of audit data for such a purpose.

Reasons given at that time included variations caused by different patient populations, different ways of performing audits, and that the

results would not be statistically significant for low to moderate volume facilities.

The end result was that while the concept of competency testing was attractive, no such test existed, nor was there a reasonable likelihood that such a test could be developed in the near future. FDA, therefore, implemented the first approach, namely requiring certain levels of specific mammography training and experience.

In the vast majority of cases this approach has worked well. However, we have encountered a small number of situation where a problem is detected in a facility due to a personnel issue. These personnel meet our requirements. However, there still may be problems with physicians interpreting mammograms, technologists performing mammograms, or physicists conducting surveys.

I would like to describe two examples illustrating the problem. The first involves a situation where a facility continues to fail the accreditation body's review of clinical images despite having gone through various corrective action plans.

While we have prevented these facilities from providing mammography services during this process, individual personnel could be providing services at other facilities.

In addition, multiple physicians, technologists, and medical physicists may be providing mammography services at the problem facility and this can lead to difficulty in determining who among the personnel at the facility are responsible for the problems.

The second example deals with a situation that has recently come to light. A facility that participated in a state program providing services to underserved populations was identified as being a significant outlier on the basis of its medical outcomes audit data.

It's important to remember that this type of data is not collected by FDA or the accreditation body and was available in this case only because the facility participated in the state program.

Further investigation by the state that included a review of clinical images suggested

multiple problems at the facility. This then led the state to initiate a patient notification program not only at this facility but at all the facilities where the involved physicians interpreted mammograms.

FDA would like the committee's input regarding if under MQSA it is appropriate for FDA or states to implement specific actions regarding personnel competency outside of our current facility based program.

DR. MONSEES: Any questions before we begin the discussion specifically for Dr. Finder on this issue from the panel?

Yes.

DR. MENDELSON: Ellen Mendelson. What exactly were the problems that were identified with respect to the decisions and their interpretations?

DR. FINDER: Well, that's a very good question. Some of the details about this when they started investigating this facility, the first thing they came up with was the fact -- and I'll preface all these things with allegations at this point.

As part of the program the facility was

supposed to be doing clinical breast exams which they were charging the state for. One of the allegations is that they never performed these clinical exams and the issue of fraud was brought up.

In addition, the state went in and examined a sample of films from this facility. Again, the allegations are that the image quality was poor, significantly poor.

The other issue was, mentioned in what I said before, that there was significant outlier in terms of their audit data. There are some allegations that question whether these mammograms were even read appropriately. There are a whole bunch of allegations.

From our standpoint the major one that we were concerned about was the clinical image quality and the allegations of missed breast cancers.

DR. MONSEES: Okay. With that, I would like to open for a panel discussion regarding some of these things. Keep in mind that we've already heard from Dr. Dempsey who is a member of the panel who felt that it was the ABR that was the best organization to

review at least physician competency and suggested that a meeting be convened perhaps including representatives from the ABR, the ACR, the FDA, and the SBI regarding whose responsibilities and possibly strategies for improving interpretive skills, at least.

Dr. Dorsey, who previously -- was he a member or was he a consultant?

DR. FINDER: He was a consultant.

DR. MONSEES: -- consultant had written again that the safeguards regarding physician competency have been in the written and oral boards and then certain requirements by the FDA in order to become an interpreting physician.

That he was concerned about using audit data -- we've heard the same comments from Dr. Destouet -- as a measure of competency. And that there are other issues surrounding this regarding whether a test would actually be a good measure, whether audit data would be a good measure because there's so much variability depending upon what type of demographic are in that area or lots of other

considerations that would affect the interpretation of the audit data.

Then the question of a test done. Dr. Dorsey brought out that there were approximately 20,000 interpreting physicians in the United States. Even if we had a test right now, it would be very hard to apply that test to 20,000 individuals.

With those things in mind, let's hear from panel members regarding their thoughts on this. Then I will turn to some of the people in the audience to have them comment again. Who would like to start? This could be a very short discussion.

MR. MOBLEY: I think this is the point I would bring up my comments earlier regarding the use of the medical audit outcome and suggesting that information could be gathered and used much as the information that we were talking about earlier relative to inspectors.

Obviously you understand that it's difficult. I mean, it's not like the optical density or some of these other things where you can just sit down and say if it's outside this, you've got to do

something. But it certainly can be used as an indicator for further evaluation and you can determine is this a valid outlier or is there a real problem here.

I think it could be used and utilized in that sense. It also could be utilized, and I just thought of this as Dr. Finder was reading his information there, it could be used as an information tool for facilities themselves.

How does a facility know where they stand when they collect this information? They only can measure against themselves. They can't measure against anybody else unless they just happen to know somebody and call old Joe over here and say, "Joe, what does your information look like?" Then they've got two points of measure, not a very good method for comparison.

DR. MONSEES: In fact, there are bench marks that are out there that are published. In fact, one of them is in the BiRads Illustrated Atlas. There is an explanation for an audit and where recommendations for bench marks are.

An individual practice can if they produce either a simple audit or complicated audit, they can bench mark themselves against the published literature and against some expected standards. Those things exist.

DR. FINDER: Okay.

DR. MONSEES: Then there are lots of things that have to be factored in so that one practice makes sure that they are comparing their apples against other apples rather than apples against oranges.

I've seen all too many practices compare their screen and diagnostic data to screening data. In fact, this panel discussed whether or not the FDA should mandate separating screening from diagnostic data.

As I recall, the FDA does not stipulate that a practice needs to separate their screening data from their diagnostic data. If that's the case, one cannot compare one practice against another. It would be totally useless. I can't compare what my yield is in a screening population to somebody else's yield if

they don't differentiate.

I think without a certain infrastructure, us all collecting the same thing, we can't start to do this. I think there is a lot of benefit to having some voluntary collection of this data and then comparing this to the National Mammography Database.

Did you have your hand up, Dr. Mendelson?

DR. MENDELSON: I did. You said much of what I wanted to say also. I do want to say, too, that many of the CME courses that are given and are required by MQSA cover that topic, how you evaluate, what you're doing, reasons why cancers are missed, how to overcome them.

All of those things and then your own statistical self-audit and how to do it are topics for discussion. I think that at almost every meeting including the major national meetings, the Radiologic Society of North America who has refresher courses, that deal specifically and in detailed fashion with these topics.

I think that no physician, no radiologist who reads mammograms wants to miss breast cancer.

There is nothing in it for them to do that. There is a commitment to patients not to do that. It's the outlying facilities that Dr. Finder has brought in to exemplify the need to address a problem in rare instances that I think we are looking at. We are not looking at everyone.

The other point that I would like to make is that there's no precedent in government regulatory statute and policies for licensing of physicians. In fact, if there were some federal way of licensing physicians, some of the state boards of medicine and the way that the license to practice as a physician and surgeon might be more efficiently done and with some consistency.

But it's not there. Why would we pick out mammography to start this? The enormous infrastructure that would have to be erected to deal with such a thing would be almost impossible to do. We have the American Board of Radiology, which is the specialty board in the requirements, that enable you to interpret mammograms initially.

We request board certification. Board

certification before you become eligible requires that you go through a certain residency program which contains breast imaging as a dedicated subspecialty.

There is specific oral board examination in breast imaging which board certified radiologists take and have to pass. If they don't, there are other things that need to be done and they need to come back.

Recertification or maintenance of competency is mandated by the American Board of Radiology, I think, after 2004. In the future the certification will be time limited. I think any additional regulation is fraught with problems and built into the entire MQSA legislation is the eligibility and maintenance of competence.

I think we have it there. Beyond that it is punitive. I think Dr. Destouet brought up a very important point before. What we want to do is assure the accessibility of high quality mammography.

We don't want to do bad mammography but we want women and there are many women throughout the country who want to have mammograms and feel that it

is something that should be provided as a public health service and for their own protection. We don't want to reduce the accessibility.

The regulations in terms of the economics are costly to comply with in conjunction with the limited reimbursement for screening and diagnostic mammograms that we have now. As Dr. Destouet mentioned, there is a movement afoot on the parts of department chairmen of radiology departments to look at how mammography fits into all of the services that they provide.

There is not high motivation to continue these services. They are, as Dr. Destouet said, "lost leaders." I think that any further regulation of physicians' practice is an impediment. Any further impediment would imperil the accessibility of mammograms to women.

DR. MONSEES: Thank you. I agree with that. I really do.

Yes.

DR. IKEDA: Debra Ikeda. I wanted to say that I think everybody in the room obviously wants

high quality mammography studies for all women across the nation. What Dr. Finder described as the situation is of a great concern to himself, FDA, and to everybody in this room.

Regarding our decision and our discussion today, I think we have to think not only about this outlier which is an extremely concerning case, but we have to think about mammography access for women all across the nation because we are thinking about something for every woman in the United States.

Specifically mammography facilities' expectations of themselves are high and the FDA has high expectations of all radiologists because MQSA regulates that. As such, all facilities have rather high cost. Now, as part of that cost radiologists themselves must know how many positive mammograms there are and the outcomes of those positive mammograms. That is inspected on a yearly basis. Those data have to be given not only to the group but also to the individual radiologist and the inspectors have to see this yearly.

Now, there are benchmarks for that, as Dr.

Mendelson and Dr. Monsees said, the quality in terms of mammography. This information is currently confidential and it's extremely useful to the facility because they can use that as a quality improvement technique.

For example, if one radiologist is calling back too many people and their biopsy rate doesn't show as many cancers as you would expect, there has to be a reason for it. Each facility must look at that data and that is extremely important. It's also important that everybody understands that is being obtained every year.

Now, if you're going to try and apply that to the entire nation, it could be very difficult and the reason it can be difficult is because, as we've heard before, different facilities are different.

Somebody who does only screen mammography with very few cancers may not have as many cancers as another facility. For example, Dr. Destouet, I heard this morning, does 100,000 mammograms.

Congratulations. You must be very tired at the end of the day.

At my facility we do about 10,000 mammograms a year. Now, if you took Dr. Dorsey's number, 6 to 8 per 1,000 or I think he said 4 to 6 per 1,000, you would expect about 60 cancers per year. In 10,000 mammograms we have 450 new cancers and that's because we are a facility that has a population heavily weighted with cancers because we are a referral facility.

Does that mean that my audit data is going to show that I'm biopsing too much because almost everybody that walks in my door may have cancer because of their risk factors. Does that mean that the person who is doing screen mammography in a population of very young woman, I think 40 is young, have a different biopsy rate. Does that mean that that person is doing a worse job than me?

I think that if you start to audit your data without taking into account these varying populations and then try and apply one type of audit to every single facility, we may not be doing the American public a very good favor because there's different ways of doing audits and there's different

ways of doing statistics and they may not be meaningful for that facility.

I think the way that FDA has suggested doing this in getting the data and then making each facility do their peer review process is important.

The one thing that I was concerned about is what Dr. Finder said. He said that the clinical images were poor and that this audit data showed that they weren't getting good images.

It makes me wonder if they weren't getting good images and then they couldn't see the cancers. As you know, mammography interpretation really is sort of an art. It's hard to see the little tumors and it's not like black and white.

My concern is two-fold. One, the data that is collected if it is decided to do some sort of competency with audit data is that those data may not be meaningful. Second, I'm concerned that the cost of mammography are already very high. Many places have a disincentive to do mammography.

In fact, one of the reasons places do mammography is to try and get contracts with HMOs.

I'm just trying to be realistic. If the cost of mammography keep going up, and some of it has to do with either trying to increase competency by testing or some other means, I have no idea, or another audit.

Then I'm concerned that's going to limit access for all women in the United States because people may not end up doing mammography because it's starting to cost them so much. That is my great concern. I don't want to limit access to woman because of something that we do here. I would like to do something meaningful.

DR. MONSEES: Yes.

DR. NISHIKAWA: Bob Nishikawa. I think at this time since there's no way of evaluating personnel competency, there's no reason we should -- MQSA should think about doing that. On the other hand, I think there's a great need to do that and there should be someone trying to figure out how to do that. I think the arguments presented that try to describe ways people can do that now are inadequate.

For example, comparing your MQSA audit data to published data is one way you could do that.

At the same time people have present arguments today that you can't take audit data from different places and compare them because it's apples and oranges so I don't see currently a way of doing that. I think in the context of this committee and this discussion I don't see any point of doing it.

DR. MONSEES: I think that it is possible to learn from the audit data as long as you realize that you could have variances from it. If you look at the published articles that are out there and the range of where you might want to be, certain measures that you can use of your success, whether it be sensitivity if you have access to get sensitivity data.

This, of course, is not required by MQSA but we're talking about just reviewing your own audit data or using surrogate measures. One can look at, for example, the average age of their population and whether woman have been screened before and what percentage are and use that to see where you might fit compared to published data.

There are ways that one can do that. It's

very labor intensive to do that. If there were a monitoring organization, it would take a huge commitment of very knowledgeable people to be able to look at other people's audit data and see where does it fit.

I think if there's an internal commitment in an institution and knowledge and understanding, then I think you can make sense out of looking at other benchmarks and comparing yourself to those benchmarks. I think it's certainly possible to do.

DR. NISHIKAWA: Is it worth putting in the guidance that it's recommended that people do that then?

DR. MONSEES: The only thing that MQSA stipulates right now is that people collect their outcome data on their positive mammograms. Some of the things that we're talking about that are quality measures that good practices are using they are doing entirely on their own on a voluntary basis which we all applaud.

That is, looking at their screening population, their call-back rates if they don't have

access to sensitivity data, surrogate measures. None of those things are, in fact, even in the MQSA regulations.

When Dr. Dorsey specifically talked about the PPV-3, the reason he addressed that was because that's the audit data that MQSA basically asked you to do. Of the patients that you sent a biopsy, what percent are cancer.

The reason that he made that point is that you can look at two practices where somebody's got all big cancers and somebody's got little cancers and if there are fewer little cancers in one practice than the other, even though there are more cancers, it doesn't mean they are doing a better job just because they have more cancers.

With what FDA asks us to collect now you can't do the highest measure audit. That we all know. I think that if it comes from within and if through education and voluntary participation, one can achieve a higher level than is even expected now from MQSA. Did I make myself clear?

DR. NISHIKAWA: Yes, that was perfectly

clear. I'm asking whether in the guidance we can make recommendations that people collect these other data that will allow them to analyze how they are doing better.

Right now I'm assuming the audit is collected -- I'm not sure why it's collected since nothing is done with it other than someone looks at it and --

DR. MONSEES: It's not collected.

DR. NISHIKAWA: I mean collected within the clinic. However you want to describe that. Not collected.

DR. MONSEES: Right.

DR. NISHIKAWA: But then an inspector comes and sees, yes, they have that number and that's the extent of it.

DR. MONSEES: No. Actually, there's an auditing physician according to the regs. There's an auditing physician who needs to review the data and report back on the facility as a whole and to each individual radiologist who is an interpreting physician regarding their performance. There is

somebody responsible at each facility.

DR. NISHIKAWA: But that number, according to Dr. Dorsey's argument, is very difficult to interpret.

DR. MONSEES: It is if you take it in isolation but if you take it in the context and with understanding of the process and what it means to that individual facility, I think it's quite meaningful.

Yes.

MS. HAWKINS: Patricia Hawkins. When this question was mailed out, of course, it's very disturbing. I've given a lot of thought to it and actually in terms of competency and so forth.

I have spent my first 16 years in public health as a public health microbiologist in a very hands-on profession and one can pass a competency exam and appear competent on paper, but sloppy techniques, technicians who don't take the time, persons who just are just unethical, it appears to me where our problem may be surfacing.

I think that facilities have to be held liable for the folks they hire. It is the facility's

job to oversee, to supervise, and to know when folks are not doing what they should be doing.

I have worked, as I say, in hands-on and have seen many microbiologists, a very specialized field. I know that from an exam standpoint certainly they would come out with flying colors, but to see their techniques on the bench, to see them at the microscope, you should review a slide and do so many ups and downs and they are taking short cuts.

Those are the types of things that have to be overseen from within that facility. I think once facilities realize that they are going to be themselves held responsible for this, that perhaps their accreditations may be jerked because of this and they will see it from a different light and so forth.

It's a difficult question but as in any industry, you're going to have bad seeds that are going to come in. I think, too, when we get to problems where persons are handcuffed and taken off to jail for Medicaid and Medicare fraud, sometimes that is a way to clean up the business and so forth.

I just think it goes back to the facility

and their responsibility to be responsible for the people that they have hired to do these jobs.

DR. MONSEES: Yes.

DR. LEE: Amy Lee. I have two kind of disjointed comments and a question. The first comment is about the outcomes data. I agree with the folks who said it's like comparing apples to oranges when you are trying to compare across facilities.

However, in the business world they also use benchmarks and one way of using the outcomes data is comparing it against your own benchmarks, the process of continuous quality improvement where you try to get baselines and try to constantly improve your quality.

This way you might be able to use the outcomes data at least internally to try to continually increase your quality of your work. That was the first comment.

The second comment has to deal with the access issue. I was pretty disturbed by the comments that Dr. Finder had about the two incidents. One of the reasons I was disturbed because, as was said

before, all women deserve to have good quality mammograms. When there is a facility that possibly or allegedly is not giving good quality mammograms, then that's not good.

On the other hand, if it's a facility in a rural area, and I believe Dr. Finder said it was a facility that provided mammograms to underserved woman, it's disturbing, too, that if that facility closes down, those woman may not have access to mammograms.

At the same time, they need to have access to good quality mammograms so it's kind of a difficult situation to deal with. I do applaud FDA's effort at trying to continually try to increase the quality of what's going on now.

Which kind of leads me to my question. That is the question about competency. Within ABR or ACR or possibly state medical boards, is there a mechanism if there's a question of competency to try to either increase the competency or something like that?

DR. MONSEES: Would you like to address

that, Dr. Mendelson?

DR. MENDELSON: Within the American Board of Radiology there are some subspecialty areas that have certificates of added qualification. Their fellowship trained subspecials will take an examination, another oral examination at some time during their careers. Or if they are relatively recently graduated residents, it would be after their fellowship.

It is not an existing program for breast imaging at the current time and the ABR has decided at the current time for a number of reasons not to take on any additional programs in subspecialty certification.

They exist, just for your information, in angiography and interventional radiology, in pediatric radiology, in neuroradiology, in musculoskeletal imaging, and in abdominal imaging.

DR. MONSEES: There's always recourse, it would seem, to the State Board for the Healing Arts because there are all kinds of quality issues throughout medicine obviously.

Mammography, which some people say may be the most regulated, certainly is not the only thing that people might find some concern with regarding not only radiologist but other types of things pertaining to breast procedures; breast surgeons, radiation oncologists, medical oncologists, etc.

There's always an appeal to the Board for Health Arts regarding somebody's competency. I would presume that they would take that very seriously in any particular state.

Yes.

DR. LEE: Amy Lee again. I would suggest then with regards to competency of the radiologists then to use the existing mechanisms that are in place rather than try to institute a new one because it sounds like there are mechanisms in place to deal with this.

The incidence that Dr. Finder related to us sounded like there are some other checks and balances that actually found the incidents out rather than radiologist problems.

DR. MONSEES: I'll just make a brief

comment. The other important thing is that, as Ms. Hawkins correctly pointed out, the regulations may not find somebody who's a bad apple because they may pass a test or they may meet the qualification. Regulations are not going to find every last bad apple. We just have to rely on them to set certain standards and hope that there are ways when things are combined to find those people.

Yes.

MS. ELLINGSON: Nancy Ellingson again. We are addressing primarily interpretation accuracy.

DR. MONSEES: Yes, we have been talking about that primarily because we are talking about protected audit data and whether that could be used. But, in fact, it sounds like the issue here is larger. FDA is asking us other personnel competency. Bad mammograms doesn't mean that it's the radiologist's fault.

MS. ELLINGSON: That's what I want to address.

DR. MONSEES: It could be anybody's fault at that facility.

MS. ELLINGSON: The rubber meets the road when the mammogram is made and turned into the radiologist and the radiologist can't read something that's not there. I understand that the primary cause for rejected clinical images is positioning and compression and not including the posterior breast on the film.

That isn't the radiologist's fault unless they monitor this on the same patient year after year and they work with that technologist and say, "You didn't include as much breast as other technologist did."

That is the critical issue is getting all that breast on the film. I don't have an answer but I definitely believe that some competency type of checking should be done with the mammographers because that's where it all starts.

DR. MONSEES: One of the comments that I think Dr. Destouet made on this point and that is it's a team of individuals that are responsible for image quality. The facility gets the certification and needs to make sure, as we were talking about in some

of the guidance today that, say, for example the facility has a certificate and the radiologists are just contracted to read the films, that all of those requirements are met. Actually the rubber does hit the road with the lead physician at the facility. That person is the named person who oversees all the quality assurance. Right?

MS. ELLINGSON: Yes.

DR. MONSEES: That's why I wanted to make sure that in that situation that was put in the guidance, that if a facility owns a certificate and they have a physician group that reads for them, that they still have to find who is going to be overall responsible at that facility because that person needs to give feedback. If your films aren't good enough, you need to do something about it.

DR. FINDER: Dr. Finder. I just want to emphasis again that we are talking about all personnel categories and that the reason, I think, everybody is focusing a lot on the physician is, (1) because the cases I brought up, and (2) one could make a case that if you've got a technologist who is not performing

well, if there's a radiologist or interpreting physician who's looking at those films, that person will not let them go through. They will be repeated. Something will happen.

There are a couple of issues that one should also consider. We're not only talking necessarily about image quality here. There are some allegations in terms of some of these cases about interpretation and that's a whole other issue, too. You can have great looking films and if you don't read them right or you don't look at them and send out reports, that could be a problem.

DR. MONSEES: You can also have somebody who reads a mammogram as positive and the surgeon, and this certainly happens, who says, "I don't care. I can't feel it. I won't do anything." That's not regulated by the FDA and it's probably not good medical practice.

It doesn't come under MQSA but it's important pertaining to the issue of the timely diagnosis of breast cancer. There's all kinds of things we can't catch here. I tend to feel that all

of the appropriate things are in place if people use the information. You can't force them to use the information.

Yes.

DR. YOUNG: Don Young. Just a couple of comments. I think without question the public expectation is that their mammographic studies are going to be properly performed and properly interpreted. I've been doing this a quarter century. One of my favorite statements is it's 95 percent technique and 5 percent interpretation.

There is a watchdog group out there that's unofficial. It's called the trial lawyers and the bad apples do surface and a lot of radiologists recognize that they're not competent interpreting mammographics and they drop out.

DR. MONSEES: That's right. They self-select. The people who are in the business tend to be people who really want to be in this business. Otherwise, there's very little motivation to do it unless you really like it. They do tend to self-select.

DR. MENDELSON: Just another comment or two. Yes, the trial lawyers are there waiting at the door and it's not a very good way to enforce high quality. I do think, though, that many of us who do read mammograms are credentialed through hospitals. The hospital medical staff offices will check credentials.

Credentials include the national database. If you have many suits pending against you, there will be some explanation of what this is all about with respect to your own practice of medicine. It's not good to get into that, I think, but it is there as a check system.

There was one other point that I did want to make. Oh, yes. About the imaging quality shifting again from interpretation. I do agree that you can't make a good interpretation, one that's reasonable without looking at an excellent mammogram from technical standpoints, positioning, exposure, everything that goes into the making of a good examination.

But through the accreditation programs

there are spot checks of facilities and sometimes in the physicist's evaluation of image quality. Then the evaluation of the clinical images by mammographers who participate, or mammologists, I guess, I should say, who participate in the accreditation program.

Things can be turned up about a particular facility. As an educational benefit, there may be a spot check on a facility in an attempt to send a team, a practicing radiologist, a physicist, technologist to a facility to help them in producing better images and to try to troubleshoot what seems to be going on.

I think we have to rely somewhat on our accreditation process. I think it helps. We have things in place and I couldn't agree more that one person needs to take the responsibility and it is that of the lead physician at a facility who really needs to look over all aspects of what the facility provides.

DR. MONSEES: Regarding trial lawyers, I just want to make the comment that there's been a lot of detriment to the profession from the trial lawyers lurking in the United States, and that is that many

facilities make that decision to lower their threshold for recall and the recall rates are probably inappropriately high in the United States compared to in Europe because of the fear of litigation. So, yeah, they are out there and they have also caused, I think, some damage and we need to be aware of that.

Regarding audit data that might be used or collected in a particular area, I think that we all want to make sure that this is used for quality measures and that it is protected and not discoverable and cannot be twisted or turned by trial attorneys in a court of law in a field that's already too filled with peril.

I think that is something that we really need to consider about anybody that benchmarks or considers giving their data to the National Mammography Database, that it is still protected and not discoverable in a court of law.

Yes.

DR. DOWLAT: Dowlat in Chicago. I'm a surgeon and my practice is almost entirely breast surgery. I receive a lot of the reports and the films

on a daily basis, something like 40 or 50 a week.

Comparing with 10 years ago the reports are much lengthier. At least half, if not more, of it is legal language. I don't know whether the FDA can do anything about that but that is some problem that you just talked about.

The other thing is that you get too many recalls because again of that background fear of missing a cancer. You get a lot of recalls that I personally think is unnecessary but that puts women under distress because of possibility of slight change in the mammogram asking them to come back in four to six months time.

I have one question for you and that is the variability in the labeling of these films. Have we not standardized the mammograms with regard to the name of the facility, name of the patient, date, and so on? The films come to me with half a dozen labels on them. Is there anything that can be done about it?

DR. MONSEES: Do you want to comment on that?

DR. FINDER: The regulations do specify

what has to be on a film and how they should be labeled. If there's a problem, let us know and we'll follow up on it if you've got a specific facility that's doing something that isn't appropriate.

I mean, those are things that are checked as part of the clinical image review process by the accreditation bodies. If you are aware of a specific example, I would be happy to look into it.

DR. MONSEES: Yes.

MS. HAWKINS: Patricia Hawkins. One other question that Dr. Finder posed here is one that has come before this committee during my tenure and I was not satisfied with how it was left or answered the first time. It has to do with how should we deal with personnel that practices at multiple facilities.

At that time I felt that persons who practiced at facility A, B, and C, if there is a problem at facility A, then it affects facility B whether or not facility B has had any problems. I just don't see how in the long term it does not have some impact upon the quality of facility B.

I really think that should be addressed to

look in terms that if you have personnel who is practicing at multiple facilities, if they are making mistakes or errors in one facility is that those other facilities are in danger. Maybe not that day but certainly the next day or the next week.

People are not sloppy in facility A and then unsloppy or nonsloppy in facility B. If you're sloppy, you're sloppy and so forth. You just continue to be sloppy. I think that instead of the situation the way it is that a person in facility A could then leave facility A and go on to B, C, and D.

I really think that is an issue where that individual definitely should be -- facility B should be notified as to what is going on in facility A and so forth so that person in charge of quality assurance can take appropriate actions.

DR. MONSEES: The other side of that coin, I might just say an anecdote from my facility. We have five units under one facility, under one roof. Actually six. Then we have a van which has a different facility number.

I have to produce separate audits for the

FDA even though it's the same exact personnel from the medical physicist all the way down. I would like to put all my audit data together because it makes more sense statistically.

Plus my recalls from the van come back to the other facility. Yet, I can't put it together and it doesn't make sense to me either. The way you write regs unfortunately can't apply to all situations.

I don't know how to please this situation and please this situation and do all those things. We hope the FDA can please everybody but they probably can't. Just to present that.

THE COURT: I can guarantee you we can't please everybody. I did want to bring up one point. I know we discussed some of these issues already but now I would like to try and get a little into the details of how do we deal with the situation that we've got.

Whether FDA does some of these things or not, it appears that some of the states are already taking some of these actions. They are using audit data to take actions against facilities. We have no

direct control over the states.

They cannot operate under MQSA under their own state authorities. Does the committee have any idea or suggestions about states that decide to use audit data, for example, to start investigating facilities?

DR. MONSEES: Can I ask a question about that?

DR. FINDER: Yes.

DR. MONSEES: I was unaware of that until you read Dr. Dorsey's letter that there were states collecting. Under what legal authority are they collecting? Is this a law that is mandated in that state or is it just the Department of Health that just decides to do it? How do they have the authority to collect audit data?

DR. FINDER: That's a very good question. The example that I gave, the reason that this data was available to the state was because they were part of a CDC program and this audit data was part of the program so the state was then able to look at that data and use that.

As I said, we don't collect the data so it isn't something that FDA if it wanted to could use audit data to investigate a facility. We don't get that data. But there are some states and it may be because the facility is part of a CDC type program or some other state funded program.

Or it's possible, although I don't know for sure, that the state could have its own laws requiring that this data be collected. We don't collect it but obviously some of the states are getting this data somehow.

DR. MONSEES: On a subpopulation that may be in some CDC program or something rather than the entire population.

DR. FINDER: For all I know it could be they have the ability in the entire state but I don't know that for a fact. We do know that in these type of programs where the audit is a part of the program, this data is collected. That's another issue I think you might want to consider.

Under the FDA program the facility is the one that goes out and collects its own data. There's

nobody else that necessarily collects it for them. In some of these others it may be a centralized group that collects the data for an entire group of facilities.

In a situation where the facility collects its own data, you may want to also consider about the fact that a facility may decide in its best interest not to bother to collect this data if it's going to be used against it.

That is incentive in some manner if that's going to be used against them. We have no way of dealing with that because there is no national organization that collects the data outside of the facility. These are all facility initiated programs.

I go back to my first question which is is there something that FDA should be asking states to do or not to do when it comes to this situation of using data because they are doing it. That's how we got this case.

DR. MONSEES: Yes.

DR. IKEDA: Debbie Ikeda. Dr. Finder, I wanted to know if the facility that you're talking

about, I understand it was part of a state or a CDC program in which the facility actually agreed to provide the data either as a part of the government program, or as part of a grant, so that there was prior to the collection of the data actually consent given by the facility to release the data to the state.

I am a little concerned that it is possible that states may demand the data based on some law or state regulation that states that they can get that data. It seems to me that this particular facility agreed prior to obtaining the mammograms that they were going to release this data.

That is very different from a law or regulation that states that if you do mammography in the United States, that you must release that data. I think it's too different situations if I'm correct.

DR. FINDER: I agree with you. I don't have all the full details about it but my understanding is that this facility voluntarily agreed to participate in this program. Part of that program was to have this audit data available so it was, in

effect, a voluntary situation as far as I know.

Again, I am not aware of any state that by law requires a facility to release this data. But I can tell you that somehow some states are getting this data, either through a voluntary thing or whatever, and they are using this data.

DR. MONSEES: Do the representatives from the any of the accrediting bodies have any knowledge of states collecting this data? Okay. No move to that.

I'm going to give you the opportunity, Dr. Destouet, to make any additional comments if you want now after the panel's discussion. Do you have anything else that you want to add to what you said before?

DR. DESTOUET: I think it's been well discussed.

DR. MONSEES: Okay. Any other comments here from the panel? I would like to hear everybody's opinion. If you have something else you need to say, I would like to hear it now.

Who are you pointing to? Somebody from

the FDA wants to say something? We would be happy to hear from you.

DR. BARR: Helen Barr, FDA. I pulled Charlie aside and asked him to try and regroup because I think the problem is, as Charlie said, there are states out there. Everything you said about audit data I agree with you as a former practicing mammographer.

Be that as it may, there are states out there using the information to shut down mammography facilities. If you look at the CDC program, there is much potential to use that data and a lot of those are going to be in underserved patient populations.

Certainly not that I want the FDA to get involved with that. I think that your recommendations on that front are pretty clear, but I think somebody is going to have to be proactive in coming up with something, whether it's adding mammography, a certificate to the American Board of Radiology exam, or recommendations that this be dealt with by the state medical boards because the fact is that states are using this data.

To address what Ms. Hawkins said, there are also states that are looking at the issue that you raised, that physician in facility A has a problem and under state authority they are taking it upon themselves to look at facilities B, C, D, and E where that physician practices and see what's going on. These issues are going on out there despite everybody's general agreement that the data as it stands now might not be particularly useful.

DR. MONSEES: Sure. Go ahead.

She would like to ask you something. Stay there.

MS. HAWKINS: Am I getting the right impression here that the CDC breast and cervical cancer projects, that the quality in those programs is not what it is under persons who may be privately insured or fee-for-service?

DR. BARR: No, I don't think that's the correct impression. I think the impression you should be getting is that those programs are required under the grant to participate to collect outcome data.

At least one state, and there may be other

states following suit, monitor that audit data and decide that this particular facility is an outlier in the number of cancers that they are detecting.

Based on that information began an investigation that led to other issues of image quality and things like that. I don't think we can say anything about the quality of mammography in CDC programs. To get the grant they have to be MQSA certified facilities.

DR. MONSEES: Do we know about any other closures other than this particular instance here?

DR. BARR: That's the only instance we know of so far.

DR. MONSEES: So we think we understand they were outliers. They were people who may have committed alleged fraud and other things.

DR. BARR: Sure. And the fraud issue came but the issue that stimulated the investigation that led to the allegations of fraud and the allegations of image quality stemmed from a review of audit data and a decision that that audit data represented an outlying situation.

There are people out there looking at audit data and making decisions to investigate facilities based on the audit data.

DR. MONSEES: Or it could have been delayed but it could have been some other whistleblower at a later point in time.

DR. BARR: Absolutely. I'm not saying that's the only reason this came to light but in this particular situation it was the audit data that led to the investigation. It was a review of that data.

DR. MONSEES: What else does FDA want to hear from this panel on? Do you have any specific questions you want to phrase in a particular way? Do you think we've covered everything that you want discussed here? Am I asking you? Is this the appropriate person to be asking? The buck stops with you, right?

DR. BARR: No, it actually stops back here. I think at the beginning -- Charlie, maybe if you can go over again your questions and sort of focus. Then Charlie just asked another one. Do you have any recommendations for us to make to these

states that are out there doing this, which they can only be, recommendations.

DR. MONSEES: Going back to that respect issue again. Whether or not they listen to you.

DR. BARR: Then I think if Charlie could reiterate his questions that he posed at the beginning, that would be helpful.

DR. MONSEES: Okay. All right.

So do we want to go back over that, Charlie?

DR. FINDER: There are a couple of things that we want to go over. One is the issue about how we deal with states that are taking it upon themselves to either use audit data or some other mechanism to further investigate facilities.

Another is the issue of determining who in a facility if it's anyone may be responsible. The typical situation can be something where a facility may have a clinical image problem but you've got 10 technologists, 10 radiologists and those people may all practice at different places.

Does that mean then that you have to go

out and examine all of them? How do you determine who's causing the problem at the primary facility if you are going to decide to look at other places. It usually is not a simple clear-cut case where you've got one person doing one thing, one technologist, one physician, and you can clearly identify where the problem is.

I also bring up the issue about if there's a clinical image quality problem, whose problem is that? Is it the technologist or is it the interpreting physician or is it both?

Obviously if you've got a bad technologist, you're going to have a bad film. But if you've got somebody above that, the interpreting physician who says, "I'm not going to let this continue. I'm going to stop it here. You have to repeat it," it won't necessarily negatively impact on the patient.

Whereas if you have both of them with problems, that's usually where we have the problem because these bad images are read and interpreted when they shouldn't have been. They should have been

repeated.

Who do you go after in terms of who is responsible? Who should get training if that's considered reasonable to do that? There are a whole bunch of questions if you get into this competency area that need to be addressed. From what I'm hearing from the committee it's a very difficult issue obviously. That's why we came to you to ask your opinion.

What, if anything, should we do in the meantime dealing with states who come to us and say, "We've got a problem. What are you going to do about it?" What should we do about it? What should we ask the accreditation body, if anything, to do about it? Should we just pass these along to the state professional boards for them to deal with? These are all things that we would be asking you to give us your opinion on.

DR. MONSEES: Okay. Let's say you have a report of films being perhaps poor image quality or a question of interpretive skill at a particular institution. Some of what the FDA does is go back in

and investigate and help maybe along with the accreditation body to help that institution improve themselves.

It would seem to me that the contact person who would be most interested in determining whether it's an individual technologist would be the lead physician at that particular place. That person who is overall responsible who you could help.

If that person doesn't want any help and that person doesn't act, then perhaps the state board could be contacted. I don't have any other suggestions other than that. Any other insights from people here?

DR. FINDER: Another thing I would bring up, at least from our understanding of the situation, and the accreditation bodies may want to chime in here. There is a difference in terms of what they are prepared to do and how their clinical image review is set up to evaluate clinical image quality, just the image quality versus interpretation. Let me give you a brief example.

If you want to get an estimate of what the

image quality is, you bring in the images and you take a random sample. It doesn't necessarily have to be a large one.

If you are looking at interpretation, as stated before, the incidents of breast cancer may be four, five, six out of per thousand. How many images with their reports do you have to look at? How many of those images do you have to get the old films to be able to do it?

It's a much different type of evaluation than just image quality. I think it's a lot greater on the resources of an accreditation body to look at and try to evaluate image interpretation versus image quality if I'm stating it correctly. If not, the ABs can certainly chime in, but I'm getting a shaking of heads that, yes, they kind of agree with what I'm saying.

DR. MONSEES: Sure. It makes sense.

DR. FINDER: These are areas and the threshold for starting these evaluations has to be considered also. It is possible to overwhelm the resources of an accreditation body if they have to

start doing these extensive evaluations on a large number of facilities based on kind of loose criteria of somebody said the images aren't good.

Where do we kind of draw the line on that? It's an issue that we're obviously struggling with and any assistance you can give us would be appreciated.

DR. MONSEES: Do we have any definitive answers for them? I don't think so.

Yes, sir. Would you come to the microphone and identify yourself.

MR. LIPPERT: My name is Richard Lippert. I own a company that monitors about 150 private mammography facilities around the country. We currently have about a million and a half events that we are auditing.

I would like to address just a couple of things. It is very true what you're saying. There's the Baskin Robbins of medical audits out there. It comes in all different flavors. There's one very underlying fact that I think Ms. Hawkins addressed that this committee should consider.

The FDA has already mapped their way to

there in the process of getting these regulations up into place. They embraced the agency for healthcare policy and research desirable goals.

Many of the key mammographers around the country sat on that panel a number of years ago. That is a standard. We have solid evidence. We had one of our clients contact us a couple weeks ago indicating that they were contacted by one of their payers, their insurers, that their accuraries were actually doing audits on patients referred to that facility for mammography.

I think that what Dr. Finder is saying and what the folks from the FDA are saying is very true. It's coming whether you want to own up to it at this moment in time or some other moment in time.

What Ms. Hawkins is saying is very true as well. The public deserves the right to know that there is a continuous quality improvement program going in place.

I think the FDA would be well served if they would embrace this Agency for Health Care Policy and Research desirable goals, establish that in a form

of guidance, recommendations, and then encourage the inspectors when they go out to not look at numbers. Is it a recall rate of 10 percent or less. Is it a sensitivity of such and such a number.

Look at did you measure it last year and what continuous quality improvement mechanisms do you have in place now to help improve the entire system because we really are challenged with this. So we have the numbers, as Dr. Finder says. I can make the numbers go away. We've already talked about the different varieties.

What I think is paramount here is that the facilities need some help. We have general radiology facilities out there. We use surveillance techniques, some of your surrogate techniques, to get audit data because they are trying. But they need some help and where do we go?

If the FDA would be bold enough to go out and embrace something that they've already embraced in getting these regulations to place and then encourage their inspectors to look at the entire process of continued quality improvement, you may head this whole

thing off at the pass.

DR. MONSEES: Any comments from the panel on this speaker?

DR. FINDER: That's an hour.

DR. MONSEES: That's an hour. All right. Any other comments from anybody regarding the subject before we move on? Okay. Let's see what time it is here.

DR. FINDER: Somebody.

MR. LAWSON: I'm Herschel Lawson. I'm from the Centers for Disease Control. I'm the medical advisor to the National Breast and Cervical Cancer Early Detection Program. Just a couple of points of clarification.

First to Ms. Hawkins. I want you to know that the radiology facilities, as Dr. Finder mentioned, that we try to use in our program are those that have high quality in numbers of procedures done so that we can be assured that these are the best facilities available for the patients that quality for our program.

The other issue relates to the data that

are collected by our programs and that are submitted to CDC for review. Most of these data are actually collected and maintained by the states. The states do audit their data. They are required for us to follow a data quality indicator guide. We are not only interested in the data being quality but we are interested in the outcomes, procedures all being of high quality as well.

When things don't match up, when you have too many completely normal mammograms, too many normal clinical breast exams, it rings a bell and then they will do further audit of these programs.

We provide technical assistance to all of our 69 programs across the United States and territories and Indian nations to be able to do these kinds of audits and then report them to us so that we can take the necessary steps to make sure that the provision of care is appropriate.

Of course, we also notify FDA as well as other bodies that have the responsibility to maintain the quality of care. I just wanted to make sure that everyone understands that this wasn't just a

serendipity case that this was picked up.

These are data that are routinely collected twice a year and it provides the basis for which the states report both their data quality indicators and their performance indicators to CDC. Thank you.

DR. MONSEES: Thank you. The same sort of things that any practice could be doing to look at their own data and their own callbacks, etc.

Was there another comment over there? Okay. I think we're done with this subject. You want to break now?

We are going to go to a 15-minute break and then we are going to continue with small field digital image receptors, full field digital. Then the other two subjects, states as certifiers and inspection demonstration project.

It looks like we're ahead of schedule for those of you who were interested in knowing approximately how long the meeting was going to last. Thank you and see you in 15 minutes.

(Whereupon, at 2:20 p.m. off the record

until 2:37 p.m.)

DR. MONSEES: All right. Let's try and reconvene. Okay. We are going to move on now. Next topic of discussion are use of small field digital image receptors. Here we go. Dr. Finder is ahead of us again. At the head of the pack.

Dr. Chakrabarti will be speaking on the use of small field digital image receptors, Accreditation and Certification Branch.

DR. CHAKRABARTI: I don't know whether you can read. I'll read for you guys. It's a very small presentation that I have.

DR. MONSEES: Maybe you can summarize it. It's very small and the presentation will be small. All I need from Bob and Bob and all the people who are here some idea and submission.

Small field digital image receptors are currently being used in many stereotactic mammographic units. Why they cannot be used for screening mammography is due to their small size. They do have the potential to be used outside the stereotactic unit to produce digital spot compression images for

diagnostic mammography.

We would like to have your submission and idea on the following MQSA issues. These issues are not small, though.

(1) Accreditation process.

(2) Equipment evaluation and annual physics surveys.

(3) Inspection process.

I would like to remind the committee that if there is regulation required, that any system which does not have screen film modality, that means other than screen film modality, the facility must follow the quality control test and criteria established and required by the manufacturer of that modality.

In this case, we would be expecting that the manufacturer will have their QC process in place and they will have test and criteria properly outlined.

However, we would very much like to have input from you if you have used this system, or if you believe that certain test must be performed and certain things that you want to alert us. Please do

that. I'll stop here.

DR. MONSEES: Okay. So we're talking about small field digital image receptors which were primarily developed for interventional procedures but are fit to standard mammography equipment which presumably also have film screen systems with them.

Are you ready to start? I saw your hand up.

MR. PIZZUTIELLO: Yes. Bob Pizzutiello. First of all, I'm very glad that FDA is considering this issue because it is happening out there in the field. My view is that the way to consider a small field digital image receptor is as another image receptor.

We had a discussion earlier today about facilities that may use a different speed screen-film combination for doing certain types of work such as magnification studies. It's important that the patients be assured of quality imaging and reasonable radiation dose from a technical perspective.

In many respects that's the medical physicist's responsibility to be the guardian of image

quality and radiation dose. I see the small field digital image receptors as another image receptor just like another screen-film combination. I don't see the need for an accreditation process for a different image receptor.

In terms of the equipment evaluation and annual physics surveys, I do think there is a need for the medical physicist to evaluate this alternate image receptor. The comments that I had made in terms of recommendations would go back to page 10 of the guidance document 4 that we discussed earlier in the morning where we talked about alternate screen-film combinations.

Of course, the more general term for a screen-film combination is an image receptor. What I would suggest then is that for tests that are appropriate to evaluate image quality and dose, that if we just were to change that table and also include the general term "image receptor," then it would apply to the small field image receptors.

The factors that I think should be evaluated by the medical physicist in terms of image

quality and dose would be the phantom image and the dose. I think that's all. Phantom image and dose. The reason why you don't want to do some of the other tests is because some of the other tests are really more a test of the image receptor.

What we want to do is test the system using the image receptor. I would say that the phantom image and the dose. For example, the line pair resolution would not be appropriate to do because you cannot compare the line pair resolution for technical reasons on a digital system with those on a screen-film system.

The other thing I think we should recommend is that facilities follow the manufacturer's recommendations for routine quality control testing to be performed by the technologist.

Kish, I didn't realize that the manufacturers were actually required to do that but I think that's an absolutely important thing to do and it's good that the manufacturers are becoming aware of that because then we have a system in place where it's installed.

It's checked by a medical physicist under an equipment evaluation. There's routine quality control done by the technologist and annual survey thereafter by the physicist. That makes me feel very confident that the quality will be high.

DR. MONSEES: What about the inspection process? You talked about the accreditation process.

DR. FINDER: I just want to go back on the table. I just want to make sure I've got it. So you're saying a phantom image and dose. Those are the only two. You're not talking about the AC performance, kVp and thickness tracking?

MR. PIZZUTIELLO: Let's see. I'm sorry. The system artifacts is one that I missed. The system artifacts should also be evaluated.

DR. FINDER: So those three.

MR. PIZZUTIELLO: Yes.

DR. MONSEES: What if individuals are using this only for interventional procedures which does not come under MQSA but it's on the equipment? I don't know how many people are using this or doing spot magnification work or how many people are just

using it for interventional procedures. If it's interventional, does it even come under MQSA?

DR. FINDER: If it's used for interventional procedures, it doesn't at the present time come under MQSA so there are no requirements.

DR. MONSEES: So if a facility has a small field digital spot detector and they state that they are only using it for interventional procedures, then the accreditation and the inspection process don't pertain to them. Correct?

DR. CHAKRABARTI: Right. And we also are not requiring quality control but ACR has a voluntary accreditation process where they have QC and other stuff but MQSA is not involved with the interventional process currently.

DR. MONSEES: Correct. Is it your impression that facilities are using these small field detectors to do spot magnification work for diagnosis?

MR. PIZZUTIELLO: Some facilities are, in fact, doing that. It's not a large number at the present time. There aren't a large number of them out there but what they find is once they have the digital

image receptor on, they like some of the features that are offered by the digital image receptor and so they use it.

DR. MONSEES: Is the device FDA approved for that?

DR. CHAKRABARTI: Let's confine this discussion to the MQSA issue. If you want to afterwards -- I saw Bill. I don't whether he's still here. If Dr. Sacks is still here after the meeting is over, you can ask him but let's confine our discussion to MQSA issues.

DR. MONSEES: Okay. I won't go there. Okay. Any other comments on this?

Yes, sir.

DR. NISHIKAWA: Bob Nishikawa. Bob, don't you think the other factors like focal spot size and kVp should also be checked annually?

MR. PIZZUTIELLO: Well, on these machines the focal spot size and kVp are already being checked because they are all being used for screen-film systems. I don't see anything about changing the image receptor that would affect the focal spot size

or the kVp.

DR. FINDER: Well, I do want to correct one thing there. Focal spot size or system resolution. System resolution gets into an area that you can't discuss because it's after 2002. There again you are testing the entire system, not just the focal spot.

MR. PIZZUTIELLO: The reason why I think the system resolution is not appropriate is because there are no benchmarks to compare them with and it's absolutely not comparable to screen-film

DR. MONSEES: Right.

DR. NISHIKAWA: Bob Nishikawa again. However, I think it's useful to measure and compare from previous years to know whether the system's egrading or not.

MR. PIZZUTIELLO: I agree with that. You ask about the inspection process, Dr. Monsees.

I would also say that from an inspection point of view, it would be good if the inspectors would just check to see that these things have been done in a substantially similar format to when they

check the medical physics survey to see that the other tests have been performed. If the tests have been performed, that would be an appropriate function for the inspection.

DR. MONSEES: Again, only though if it's used for diagnostic work and not for intervention. Perhaps in whatever guidance FDA puts out regarding this, they would stipulate that a facility needs to state whether this is diagnostic work or just for interventional procedures because that would exempt them from any inspection on that it seems to me. Of course, they could be inspected by their state but not necessarily by the FDA inspector.

Do you need any other guidance from us? I hate to use the word guidance. Comments from us? Discussion? Does FDA need any other discussion?

MR. PIZZUTIELLO: Let me just say one other thing and I don't want this to get deep, but if somebody then says, "How do we do these tests?" Essentially the ACR stereotactic quality control manual tests that are covered under this area that I've discussed would be appropriate.

I know that you cannot reference them in regulation. If you were permitted or so inclined you might want to reference that ACR manual for those medical physicists who wanted to know how do I then go about doing this. If they are not otherwise connected with the stereotactic accreditation program, they might not know that document exist.

DR. CHAKRABARTI: Yes, I think the guidance that we got is what Bob and Bob mentioned. The only thing that I hope they agreed on that the line pair requirement would be required or not. As I mentioned before, the manufacturer will also provide us a list of requirements that they like to see are followed. The only point I'm not clear from Bob and Bob is whether line pair should be required or not.

DR. NISHIKAWA: Sorry. Whether it should specified?

DR. CHAKRABARTI: Yes. I thought you think this is a requirement as a QC test.

DR. NISHIKAWA: This is Bob Nishikawa again. I think it has to meet manufacturer's spec, whatever they specify.

DR. CHAKRABARTI: Very good. Okay.

MR. PIZZUTIELLO: I would agree with that.

DR. MONSEES: Okay. Any other comments from anyone on the panel regarding this subject? Then we'll move on, thank you very much, to full field digital mammography certification update.

We have two presenters. I'm not sure between you whether you have decided who is presenting first.

Dr. Helen Barr.

DR. BARR: Helen Barr, FDA. You may recall at our last NMQAAC meeting we described a process by which we would extend MQSA certification to facilities who applied to us to us a digital unit under their certification. This was a process that was developed in the absence of a current accreditation process for digital mammography.

I would just like to very briefly tell you that the system that we described to you last time is working extremely well. We've been able to extend a number of certifications to include digital. As an interim process it seems to be going well.

That's really about all I have to report. I anxiously await Penny Butler telling us where the ACR is on its accreditation process. Do you have any questions?

DR. MONSEES: I'd just like to know how many are out there and certified. Do you have any idea? Hopefully we have this number right.

DR. FINDER: Let me just say we not only have an idea, we have the actual number but we can't tell you.

DR. MONSEES: You can't tell me because you'd have to kill me or --

DR. FINDER: Not only you but everybody in the room.

DR. BARR: Actually, I can tell you and I cleared this --

DR. MONSEES: I don't want to die.

DR. BARR: I've cleared this with the person who really does stop the buck. GE has a web site, a public web site called hersource.com that lists all the locations where they have installed digital facilities. I don't think that quite

accurately reflects which areas have had certification extended to use digital yet. The last time I looked at the web site there were around 17 sites up there.

DR. MONSEES: So it's a small number but it seems to be working for those.

DR. BARR: Yes.

DR. MONSEES: That's the only reason I asked, just to see whether it was a smattering or was it --

DR. BARR: Now I have to kill you.

DR. MONSEES: Bailiff, please take her away.

MS. BUTLER: But not until I get started. I'm Penny Butler. I'm with American College of Radiology. I just want to give you a brief update on what's going on with the digital module to the mammography accreditation program.

We have a subcommittee on digital mammography accreditation that's chaired by Martin Yaffe. I know he's a Canadian but it still works. He's from Sunnybrook in Toronto. The committee consist of other medical physicists and radiologists

who all volunteer their time in order to develop this accreditation module.

I want to explain that the digital module, like our other accreditation program, is a male testing process. The technology in digital is more complex than conventional mammography and the technique factor control design complicates the testing.

In addition to that, the instructions that we provide have to be clear, concise, and relevant to the technologists who are going to be the ones really conducting the test. As we develop our accreditation module, we have to keep these things in mind.

Now, what we've done so far is we've conducted alpha-testing in the spring of this year. We're just looking at the technical parameters, not the clinical stuff yet. We're looking at phantom dose, the forms, the testing instructions. We're looking at processes to evaluate units from multiple manufacturers. We've tested these procedures with our subcommittee.

The subcommittee is currently utilizing

the results and modifying the test procedures and they are rechecking the results. We will be moving to beta testing where we'll look at clinical phantom dose in the full application. We are going to be utilizing the ACR imaging network facilities to volunteer for the beta testing.

Now, in addition to that the ACR through their standards process is also working on a very general set of standards for whole breast digital. These are in a very draft form. They are being reviewed by the various physician experts and medical physicist experts within the college. We hope to have this up for council vote in the 2001 cycle.

That is where we are with the accreditation program. Any questions?

DR. MONSEES: Questions from the panel? Comments? Thank you very much.

MS. BUTLER: Now you can kill me.

DR. MONSEES: Moving on we are going to be talking about States as Certification Agencies, an update from Kaye Chesemore. Thank you.

MS. CHESEMORE: I'm Kaye Chesemore. I'm

the States as Certifiers coordinator for FDA. Really there are two purposes here today for my talk. I want to give you just a little brief background about the SAC program. You'll notice throughout this talk I will be using this acronym SAC for the States as Certifiers program.

Secondly, I want to tell you about some of the comments that were sent to FDA after the proposed SAC regulations were published in the Federal Register. The demonstration project or pilot program for SAC is beginning its third year and will continue until the SAC regulations are final. Barring any unforseen circumstances, our goal is to have the SAC regulations final by the spring of 2001.

Two states are currently participating in the program. They are Iowa and Illinois. Several other states have shown an interest in becoming a SAC state. We think that they will probably wait until after the regulations are final.

To give you some examples, Arkansas, California, South Carolina, North Carolina, Maryland, Texas, have all expressed an interest. That list is

by no means exclusive though.

Now to get on with some of the issues that were presented to us and the comments in the Federal Register.

Let me preface this by saying that first of all we're not permitted to law to tell you how we are responding to these comments. I can share some of them with you. I might add that any topic of a regulatory nature requires that we can't give advance notice. Second, the answers are not final and, therefore, are subject to change.

We received eight letters in response to the request for comments with a total of 39 comments to be addressed. About half of those 39 comments, or 20 comments, were related to the regulations in at least a general way. The others were related to the economic impact or the paperwork reduction analyses.

The letters included comments about training, the MQSA database, the MQSA inspections, the inspection support fee, the SAC application process, the SAC evaluation process, AMR or additional mammography review, compliance, and interim notices.

I'll touch just briefly on each of these areas.

First of all, one respondent mentioned that the inspector training should be the responsibility of each individual state instead of being under FDA's auspices. Currently, as it may have been mentioned earlier, we have 250 state and federal MQSA inspectors in the field who have attended six weeks of training.

A second comment had to do with the FDA database. This respondent asked the FDA to review the system to determine whether all aspects of the system are necessary. Again, for those who are unfamiliar with MQSA, the purpose of the database is, (1) to permit the electronic transfer of information between the accreditation bodies and FDA and then FDA and the certification agencies.

In addition, it permits transfer of information to the Health Care Finance Administration (HCFA) for facilities to be reimbursed under Medicare and Medicaid. Also information is transferred to the National Cancer Institute to assist women in finding a mammography facility near their locations.

Last but not least, it allows the electronic recording of inspection results from the MQSA inspectors and the transfer of those results back to inspectors as needed for later inspections.

Regarding those yearly inspections by MQSA inspectors, another respondent commented that FDA should reduce the cost, the scope, and the time of those yearly inspections.

Another issue questioned by several respondents was the amount of the inspection support fee charged by FDA in SAC states. Just a note about that inspection support fee.

It includes cost to FDA for equipping the inspectors with measuring instruments, the calibration and the maintenance of those instruments, the design, the programming, and the maintenance of the data system, and the provision of laptop computers to the inspectors and the maintenance and upgrading of those computers.

It also includes training and certification of inspectors. It includes other costs that are not directly attributable to the inspection

itself.

Other comments related directly to the SAC application process. One example is that a writer commented that the state agency should be able to attest to adequate staffing, to their finances, and other resources rather than submitting some of the detailed reports that FDA requires.

Another asks how FDA plans to implement an evaluation of the SAC program without incurring unreasonable cost and without undue burden on the facilities.

I might add that throughout the SAC demonstration project we have been evaluating both SAC states, Iowa and Illinois, at no cost to the facilities in those states. These oversight functions have been performed with appropriated money. Thus, FDA is assuming the burden of cost.

Likewise, comments were made about the development of performance indicators by FDA to evaluate the performance of SAC states.

I would like to mention that we do have performance indicators at this time and they were

developed with the input of the SAC working group. The indicators were then distributed to all the state program directors for comment. If any of you would like to see them, they are available upon request. We will be modifying these probably as our experience with the program grows.

In addition to these comments, two other points of view were expressed about additional mammography review, or AMR. The first respondent thought that too many AMRs were being initiated. The second one felt that AMR was irrelevant in cases where a facility was performing uncertified and that you should go immediately to patient notification.

Still another comment was that the SAC regulations should not imply that a certifying agency is responsible for facility compliance. However, it is important to note that one of the fundamental premises of the SAC program is that compliance is given to a certifying agency.

Finally, some comments centered on the issuance of interim notices and the suspension and revocation of certificates within a certifying state.

Finally, though I can't entertain questions about the comments to the Federal Register notice, I would like to emphasize that the SAC program has been very successful thus far. I think that both the states of Iowa and Illinois would agree that we have had a very cooperative working relationship and we look forward to other states becoming certifying agencies. Thank you very much.

DR. MONSEES: Do we have any questions? Thank you. Thanks for the update.

The inspection demonstration project, Dr. Barr.

DR. BARR: This, too, is an update. Helen Barr, FDA. While we're getting set up, I'll just do what in our division we call a "retro" and go back to an issue that we talked about before which was the facility satisfaction survey.

My colleagues correctly pointed out to me that I didn't comment on what the results of our last survey showed. It was in the range of a 95 percent overall satisfaction with the inspection experience in the responding facilities.

DR. MONSEES: Thank you.

DR. BARR: Again, as you may recall for those of you who were here last January, John McCrohan outlined the inspection demonstration project to you where we were at that time. I would just like to update you to where we stand now.

Just to refresh your memory, the inspection demonstration project came as part of MQSRA where it was said that the Secretary of Health and Human Services could initiate such a project to see if inspecting high quality facilities at a less than annual level would affect the quality of what facilities were doing in mammography.

There were certain restrictions. One, that the program not be implemented before April of 2001; that selected facilities would get less frequent inspections; that the facilities included be substantially free of incidences of noncompliance; that the number of facilities provide a statistically significant sample; and that the inspection frequency will reasonably assure compliance with standards. Within those guidelines we've tried to develop our

program.

Part of this is a little confusing because although the Committee on Commerce anticipated, in their words, that such a demonstration project would be large enough to produce sufficient reliable data, they also said at that time that they didn't conceive of it going to more than three to five states.

Obviously, I don't think we had any statisticians on the Department of Commerce Committee because we found from our statisticians that it would be not possible to obtain statistically significant data with such a small state sampling size.

We have been working closely with the Conference of Radiation Control Program Directors, the CRCPD, to develop this project. They did an initial survey for us in two states asking them about participating. Recently we sent confirmatory letters to all 50 states plus D.C., New York City, and Puerto Rico.

As of yesterday our response is back. Thirty-four states have responded to us and 11 states have agreed to participate which obviously isn't a

huge number. Those are the states up there. Some of the states have agreed to participate conditionally based on some of the details of the demonstration program coming forward. I would like to point out that eligible federal facilities will participate in the program.

The state criteria hasn't changed since we laid it out for you last time. Basically the state can have no rules, regulations, or policy which require annual inspection of mammography facilities because if the state was going in there on an annual basis and MQSA was going in there on an every two year basis as part of the demonstration project, then it was felt that would muddy the results.

If they have any of these laws, regulations, or policies, they have to be willing and able to change them if they want to participate. They have to agree to participation. We came to an agreement that we didn't want to strongarm any of the states to participate, although with our low numbers I don't know about that decision.

Anyway, that the states inspect

participating facilities at the frequency that is designated by the demonstration program; that the states would accept modifications in their contracts because the number of facilities to be inspected would be somewhat reduced; and that during the program if any serious risk to public health were identified, that the FDA should become aware of those problems in participating facilities.

This brings up a number of related issues that we've been struggling with. Obviously right now with 11 states agreeing to participate we have a limited number of states. Only a certain percentage of facilities in each state is going to be eligible and I'll go over the facility criteria with you.

Plus, in order to not economically adversely affect states, we wanted to try to keep the number of states participating to about five percent. Let me point out that this is up for grabs right now whether that should say states eligible facilities or the states entire number of facilities. We are having a minor debate about that.

We rapidly ran the numbers and actually it

doesn't make a huge difference how you calculate that. Suffice it to say that we are looking at ways to decrease the economic burden on states for those skipped inspections.

Based on the CRCPD's initial survey of the states and the relatively small positive responses that we were getting to participate, we went to some more inclusive facility criteria which I'll go over with you to try and capture more eligible facilities.

We are still debating the exact design of what the inspection at the 24-month interval would look like. We are continually grappling with the questions of statistical significance, how many facilities we need to obtain that, whether we are going to get to that number, etc.

Facility criteria. These are ones that have not basically changed since the previous ones that we brought to you. The facility has to maintain full accreditation and certification throughout the time of the accreditation program. They have to anticipate providing mammography services during the program.

They have to undergo at least two annual inspections under the final regulations to be eligible. They cannot have received a regulatory or compliance action or be in the process of being considered for such regulatory action by the FDA. And they have to be selected by the FDA to participate.

What has changed is when we went to somewhat more inclusive criteria to try to capture more facilities, we came up with that during the three most recent inspections there can be a maximum of three Level 3 citations total throughout those three inspections. And a maximum of one Level 2 citation. That is new. We hadn't previously allowed any Level 2 citations.

That's a total of one Level 2 citation throughout the three most recent inspections and no Level 1s at all during inspection time. During the most recent inspection it has to be completely clean with no citations at all.

The five percent column here you probably want to ignore right now based on what I said about our issue of exactly how we are going to calculate

that. This is just to give you an idea of to date the number of facilities that would be eligible in the states that have agreed to participate.

Not all the facilities in the states have undergone their second inspection under the final regulations. To date we have about 1,300 facilities that would be eligible. If you take five percent of that total number, it only comes to 64. If you don't exceed five percent of the state's total facilities, it isn't hugely different from that, although it is somewhat higher.

As you can see at this point, we don't have large numbers to work with. When we initially worked with our statisticians, they kind of threw out a number of about 300 to 350 facilities would need to participate in the demonstration project that would be divided into a control group and a study group.

That was before we went to the somewhat more inclusive criteria so they are busy looking at the more inclusive criteria that we went to and seeing if that would significantly impact that ball park 350 figure that they gave us. Obviously, we are far below

the numbers we need right now.

The time line I just want to go over briefly kind of what to expect in the time line of the demonstration project. We hope shortly to confirm our list of participating states. By October of next year once all the facilities have undergone -- once a number of the facilities have undergone their two inspections under the final regs, we want to provide the states with the names of the first 50 percent of the facility selected.

This will allow a lead time to the facilities and the states of at least six months to knowing who is going to be skipping an inspection. We would distribute the letters of notification to that first 50 percent in October 2001 and select the second 50 percent when the remaining facilities undergo their second inspection under the final regs in May of 2002, notify the facilities and the project would then be implemented in May of 2002.

We are still struggling, as I said, with some remaining questions, what should be done if the number of participating facilities doesn't come up to

what our statisticians consider a statistically significant outcome.

Do we proceed with the project and use the data that we have. If we do, how do we apply that data to facilities across the country. Do we not do the project. Exactly what do we do if we get to the situation where our numbers don't measure up, at least to where our statisticians think they should be.

Again, no matter what we do, particularly if we would end up using nonstatistically significant numbers, how would Congress interpret those numbers and apply them to any laws that they would pass.

Just as a quick update, I counted there are about nine more states that have said they won't participate, although they have no law or regulation or policy preventing them from participating.

In theory if any of them would change their minds, we could capture nine more states. We also have about nine states that don't have any law, regulation, or policy that would prohibit them from participating that have not responded yet. It's possible we could capture some of those states, too.

That's where we stand at the present time. If the committee has any comments on anything like the criteria or the timeline or any thoughts on how to proceed if we don't get statistically significant numbers, I would be glad to entertain your thoughts.

DR. MONSEES: Any comments on that?

MR. PIZZUTIELLO: Bob Pizzutiello. It seems to me if you know at the outset of an experiment that the results are going to be completely inconclusive, then I don't think you can justify the time and effort and resources to do the experiment.

I wonder what, if any, incentives there are for states to participate since it seems that the only thing there is is a disincentive that when they participate in this program they lose money. We've had discussions here and elsewhere that this is a project that needs to be done.

I wonder if there might be some way to either create an incentive for states or to revise some of your criteria or use more facilities from a state so that you can at least project getting to a statistically significant sample size.

DR. BARR: We have already adjusted the criteria to be more inclusive. One of the things that the Committee on Commerce set forth is that it has to be substantially clean facilities and the purpose of the project is to see if the good facilities can go being inspected every two years.

There is some concern that if we make the criteria more inclusive, we are going to get to facilities that have compliance problems and those facilities aren't going to be a good example of what really good facilities could do.

I would be interested in hearing if you have any ideas for incentives. I think the incentive for a state to me would be even if they are against the whole idea of not inspecting annually would be to get in there and participate and see what the meaningful results show.

It may bear them out to say that you're right, we need to be in there every year. It falls apart if we're not. Do you have any ideas about incentives?

MR. PIZZUTIELLO: Yes. Two thoughts come

to mind. One is since it seems to me that the primary disincentive is financial, maybe that could be a way to somehow compensate the state for some of the lost revenue. That money would have to come from somewhere and people in the government sometimes are able to do those kinds of things.

Another would be to say if states would agree to contribute more than five percent of their eligible facilities, it could be involuntary so that a state would have to say we are willing to take more of a financial burden on.

There might be some states who are short staffed who might be happy to have a reprieve for a couple of years because in a lot of states inspectors are retiring and they are having trouble hiring people and so on. Perhaps by limiting the number -- when I look at the data if you could move from five percent to a large percent, it's not that there aren't facilities out there.

It's when you take five percent of a number, it's hard to come up with 300 and some. My thought would be to see if states would be willing to

voluntarily go beyond the five percent and then see what your numbers are like.

DR. BARR: Certainly the five percent was put in there with the CRCPD worrying about the economic impact. We have grappled with some of these different ideas. Unfortunately when we get to some of them our statisticians tell us that it could skew the results.

I mean, if a state voluntarily submits more of their facilities, then the geographic distribution is skewed and they are worried about that already with the limited number of states we have participating. I think those are all reasonable ideas but we do run into how it fits into the numbers.

It's been my anecdotal experience listening to the states, though, that the economic impact, amazingly enough, does not seem to be the primary reason for not participating I would have to say. It's philosophical in nature, I would say, for the most part.

That's not to say for everyone who is not participating. I'm sure for some states it may be

economic. A lot of them it's a philosophical issue that they don't think that we should go anywhere near and not going in yearly to facilities. Then, of course, there are the states that can't participate because of their laws.

DR. MONSEES: I would have to say that a philosophical difference is hard to swallow because this is a demonstration project. This is a very small number of facilities. We're not talking about necessarily commitment to doing this in the future. We are just talking about their participation to see whether there's any validity to dropping the yearly inspections at good facilities.

I think, as Mr. Pizzutiello does, that there's a big financial incentive to states to inspect. Our state, for example, not only charges the FDA rate but a unit charge per unit for state inspection. I think it's financially productive for them to inspect every unit every year. They make far above what the FDA costs are. I personally think that is a big issue.

DR. LEE: Amy Lee. You said that 34

states responded? Do you know why the other states didn't respond to your initial inquiry?

DR. BARR: No, I don't know yet. The deadline was September 15. It's sent to a specific person in the state that could be on leave. There also is some recent indication that states didn't quite understand and if they have lost the form, who they could get it back from. We are hoping that we can at least come up to the 50 responses, however that may be.

DR. LEE: If it's sitting on somebody's desk, you just might need to ask again.

DR. BARR: Exactly.

DR. MONSEES: Did somebody phone call these places to ask their response? Sometimes follow-up surveys are by telephone.

DR. BARR: As I said, the deadline was just September 15 so, you know, certainly we will entertain ways of coming up to our full 50 responses. I'm sure we can get there.

DR. MONSEES: Any other comments? I think we have finished our business. Is that correct? I'll

ask Dr. Finder.

DR. FINDER: Yes.

DR. MONSEES: He's a man of few but important selective words. Thank you very much for your attention. This is my swan song so farewell and thank you. Have a good day.

(Whereupon, at 3:25 p.m. the meeting was adjourned.)